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Public Health

42

PARTS 61 TO 399

Revised as of October 1, 1990

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PARTS 61 TO 399

Revised as of October 1, 1990

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Cite this Code: **CFR**

To cite the regulations in this volume use title, part and section number. Thus, **42 CFR 61.1** *refers to title 42, part 61, section 1.*

Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

ISSUE DATES

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16 ..... as of January 1
Title 17 through Title 27 ..... as of April 1
Title 28 through Title 41 ..... as of July 1
Title 42 through Title 50 ..... as of October 1

The appropriate revision date is printed on the cover of each volume.

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The contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507). The Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

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MARTHA L. GIRARD,
Director,
Office of the Federal Register.

October 1, 1990.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of four volumes. The parts in these volumes are arranged in the following order: Parts 1-60, Parts 61-399, Parts 400-429 and Part 430-End. The first volume (Parts 1-60) contains current regulations issued under Chapter I—Public Health Service (HHS). The second volume (Parts 61-399) contains the remaining regulations issued under Chapter I. The third volume (Parts 400-429) includes regulations issued under Chapter IV—Health Care Financing Administration (HHS) and the fourth volume (Part 430-End) contains the remaining regulations in Chapter IV and the regulations issued under Chapter V by the Office of Inspector General-Health Care (HHS). The contents of these volumes represent all current regulations codified under this title of the CFR as of October 1, 1990.

The OMB control numbers for the Health Care Financing Administration appear in § 400.310 of Chapter IV. For the convenience of the user § 400.310 is reprinted in the Finding Aids section of the fourth volume.

Redesignation tables for Chapter I—Public Health Service, Department of Health and Human Services and Chapter IV—Health Care Financing Administration, Department of Health and Human Services appear in the Finding Aids section of the second, third, and fourth volumes. A derivation table for Chapter V, Office of Inspector General-Health Care appear in the third and fourth volume. A derivation table affecting Part 430 appears in the fourth volume.

For this volume Kent H. Giles was Chief Editor. The Code of Federal Regulations publication program is under the direction of Richard L. Claypoole, assisted by Alomha S. Morris.

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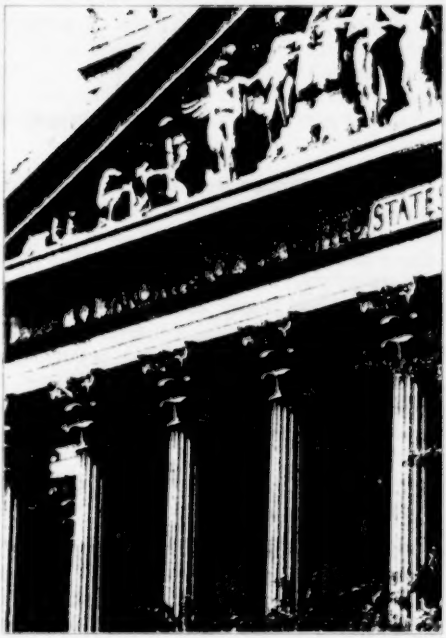

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(This book contains Parts 61 to 399)

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PART 61—FELLOWSHIPS

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Subpart A—Regular Fellowships

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, sec. 8, 77 Stat. 400; 42 U.S.C. 216, 1857g; secs. 301, 402, 58 Stat. 691, as amended, 707, secs. 412, 422, 62 Stat. 464, 598, sec. 433, 64 Stat. 444, as amended, sec. 308, 74 Stat. 364, sec. 444, 76 Stat. 1073, sec. 3, 77 Stat. 394, secs. 394, 395, 79 Stat. 1062; 42 U.S.C. 241, 282, 287a, 288a, 289c, 242f, 289g, 1857b, 280b-4, 280b-5.

SOURCE: 31 FR 12096, Sept. 16, 1966, unless otherwise noted.

§ 61.1 Definitions.

As used in this part:

(a) "Continuation award" is an award made by the Surgeon General, within the period of support recommended by a fellowship committee, without necessity for further action by the committee.

(b) "Noncitizen national" means any person who, though not a citizen of the United States, owes permanent allegiance to the United States.

(c) "Regular fellowship" means an award to support activity not requiring performance of services for the Public Health Service.

(d) "Surgeon General" means the Surgeon General of the U.S. Public Health Service or his delegate.

(e) "Continental United States" does not include Hawaii or Alaska.

§ 61.2 Applicability.

The regulations in this subpart apply to the establishment, award, and operation of all regular fellowships awarded under the Public Health Service Act and the Clean Air Act.

§ 61.3 Purpose of regular fellowships.

Regular fellowships are provided to encourage and promote:

(a) Research and training for research relating to (1) the physical and mental diseases and impairments of man, (2) the organization, provision, and financing of health services, (3) the causes, prevention, and control of air pollution, and (4) medical library and related health sciences and communication of information.

(b) Special scientific projects for the compilation of existing, or writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health.

§ 61.4 Establishment and conditions.

All regular fellowships in the Public Health Service shall be established by

the Surgeon General. In establishing a fellowship or series of fellowships, the Surgeon General shall prescribe in writing the conditions (in addition to those provided in the regulations in this part) under which the fellowships are to be awarded and held.

§ 61.5 Qualifications.

In order to qualify for a regular fellowship, an applicant must:

(a) Meet the Public Health Service requirements of general suitability, including professional and personal fitness.

(b) Have been accepted by a public or other nonprofit institution for the purpose of the activity for which the fellowship is sought.

(c) Be free from any disease or disability that would interfere with the accomplishment of the fellowship purpose.

(d) If a citizen or noncitizen national of the United States, sign and file with the Surgeon General the following statement:

> I do solemnly swear (or affirm) that I bear true faith and allegiance to the United States of America and will support and defend the Constitution and laws of the United States against all its enemies, foreign and domestic.

(e) Comply with such other requirements as may be prescribed by the Surgeon General.

§ 61.6 Method of application.

Application for a regular fellowship shall be made on forms prescribed by the Surgeon General. In addition to the information supplied by the applicant in his application, such further information may be required as is necessary to determine his qualifications and fitness.

§ 61.7 Review of applications; committees; awards.

The Surgeon General shall appoint one or more fellowship committees to examine the qualifications of applicants for fellowships and the merits of their proposals for research, training, or special scientific projects. A fellowship committee shall submit to the Surgeon General its recommendations concerning appointments. Awards of regular fellowships shall be made in writing by the Surgeon General.

§ 61.8 Benefits: Stipends; dependency allowances; travel allowances; vacation.

Individuals awarded regular fellowships shall be entitled to such of the following benefits as are authorized for the particular series of fellowship:

(a) Stipend.

(b) Dependency allowances.

(c) When authorized in advance, separate allowances for travel. Such allowances may not exceed amounts prescribed by the Surgeon General for (1) travel to the place where the fellow is to be located during the fellowship term, and (2) travel to return the fellow at the end of the fellowship term to his home or other place he left to carry out the fellowship, provided that (unless otherwise prescribed by the Surgeon General) such return travel is to or from a place outside the continental United States. No allowances will be granted for shipping personal effects or household goods and no allowances will be granted for transporting dependents, except as authorized by the Surgeon General for travel undertaken by dependents (spouse and/or dependent children only) to or from a place outside the continental United States where the fellow is to be located during the fellowship term and for return from such place or except as otherwise prescribed by the Surgeon General for a particular series of fellowships.

(d) *Vacation:* Stipends and allowances will not be increased, or be paid beyond the term of a fellowship, on account of vacation an individual might have been entitled to but did not take.

§ 61.9 Payments: Stipends; dependency allowances; travel allowances.

Payments for stipends, dependency allowances, and the travel allowances specified in § 61.8 may be made directly to the fellow or to the sponsoring institution for payment to the fellow.

§ 61.10 Benefits: Tuition and other expenses.

The Surgeon General may authorize allowances for payment of expenses,

in whole or in part, of tuition, fees, equipment, supplies, attendance at meetings required to carry out the purposes of the fellowship, or other expenses of the activities of the fellow.

§ 61.11 Payments: Tuition and other expenses.

(a) *Tuition and fees.* Allowances for tuition and fees may be made to the fellow or sponsoring institution.

(b) *Other expenses; standard or maximum allowances.* Any allowances for equipment, supplies, attendance at meetings, and other expenses shall, except as may otherwise be prescribed herein or by the Surgeon General, be paid to the sponsoring institution. The Surgeon General may establish a standard allowance or a maximum allowance for payment to the sponsoring institution for such expenses.

(c) *Attendance at meetings—fellows sponsored by Federal agencies.* Allowances for expenses of attendance at meetings by fellows who are sponsored by Federal agencies may be paid directly to such fellows.

(d) *Installments.* Payments to sponsoring institutions and to fellows under this section or under § 61.9 may be made in advance or by way of reimbursement and, except as may otherwise be prescribed by the Surgeon General, in monthly installments.

§ 61.12 Accountability.

Payments shall be subject to such requirements relating to accountability as may be specified by the Surgeon General.

§ 61.13 Duration and continuation.

An award period may be any period not in excess of 2 years. The Surgeon General may make one or more continuation awards for an additional period upon a finding of satisfactory progress toward accomplishment of the purposes of the initial fellowship award. Additional support may be provided on appropriate justification after expiration of the period of support involved in the previous award.

§ 61.14 Separate consideration of information concerning moral character or loyalty.

No information in the records or possession of the Public Health Service concerning the moral character or loyalty of a fellow will be made available to any fellowship committee involved in recommending appointments of fellows.

§ 61.15 Moral character or loyalty; reference to Special Review Committee; review and recommendation.

(a) *Moral character or loyalty; reference to Special Review Committee.* Whenever the Surgeon General has substantial evidence with respect to any fellow (1) that the statement filed pursuant to § 61.5(d) was not made in good faith; or (2) that a fellow has (i) been convicted of a crime involving moral turpitude or (ii) engaged in conduct involving moral turpitude (unless in the case of either paragraph (a)(2) (i) or (ii) of this section, it is established that the fellow is, nevertheless, then a person of good moral character), the Surgeon General shall refer the pertinent records to a Special Review Committee established as prescribed in paragraph (b) of this section.

(b) *Special Review Committee; composition.* The Special Review Committee shall be composed of a representative of the Office of the Surgeon General designated by the Surgeon General as chairman but nonvoting member, the appropriate Associate Director or comparable official of the bureau involved, the Chief of the Division of Research Grants, the Director of the Institute or the Chief of the Division which awarded the fellowship in question, or their delegates, and two additional members appointed by the Surgeon General.

(c) *Information; supplementation.* The Committee may supplement the information referred to it by such correspondence, personal interviews, or other informal methods as necessary in order to make its recommendation as provided in paragraph (d) of this section.

(d) *Review and recommendation.* The Committee shall review the perti-

nent records, determine whether there is substantial reason to believe that the award should be terminated or not continued either on grounds relating to moral character or on the ground that the statement filed pursuant to § 61.5(d) was not made in good faith, and make its recommendation to the Surgeon General in writing, with reasons therefor, accordingly.

§ 61.16 Termination of or refusal to continue award on grounds relating to moral character or loyalty; hearing.

If, after review of the recommendation of the Special Review Committee, the Surgeon General believes that the award should be terminated or should not be continued, he shall notify the fellow and sponsoring institution in writing that unless a request for a hearing is made by the fellow within 20 days after the fellow's receipt of such notice, his fellowship will be terminated or his application for continuation of the award denied. A copy of the regulations under this subpart and a copy of Part 10 of Title 45, Code of Federal Regulations, shall be enclosed with the notice. The notice shall set forth, as specifically as security permits, the grounds for the questions pertaining to moral character or loyalty. Any such request for a hearing shall be promptly submitted by the Surgeon General to the Chairman of the Departmental Fellowship Review Panel for handling in accordance with such Part 10.

§ 61.17 Termination on grounds other than those relating to moral character or loyalty.

The Surgeon General may terminate a fellowship upon receipt from the fellow of a written request for termination. The Surgeon General shall terminate any fellowship prior to the date it would otherwise expire if he determines that the fellow's performance is unsatisfactory or that the fellow or the sponsoring institution is unfit or unable to carry out the purpose of the fellowship. The fellow and the sponsoring institution shall be notified in writing of such termination.

§ 61.18 Publications.

Publication, distribution, and disposition of all manuscripts and other materials resulting from a fellowship awarded hereunder shall be subject to the conditions that all such materials shall bear appropriate acknowledgment of Public Health Service support, that fellows shall furnish copies of such publications or other materials as may be requested by the Surgeon General, and to such other conditions as the Surgeon General may prescribe.

§ 61.19 Copyright and reproduction.

Where the work accomplished under a fellowship award results in a book or other copyrightable material, the author is free to copyright the work, but the Public Health Service reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use, and to authorize others to use, all copyrightable or copyrighted material resulting from the fellowship award.

§ 61.20 Inventions or discoveries.

Any fellowship award made hereunder is subject to the regulations of the Department of Health and Human Services set forth in Title 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which fellowship funds are in fact used, whether within the scope of the fellowship as approved or otherwise. Appropriate measures shall be taken by the fellow, the sponsoring institution, and the Surgeon General to assure that no contracts, assignments, or other arrangements inconsistent with the fellowship obligation are entered into or continued and that all personnel involved in the supported activity are aware of and comply with such obligation. Laboratory notes, related technical data and information pertaining to inventions or discoveries shall be maintained for such periods, and filed with or otherwise made available to the Surgeon General or those whom he may designate at such times and in such manner as he may determine necessary to comply with such Department regulations.

§ 61.21 Interest.

Any interest earned through deposit or investment by the sponsoring institution of funds paid pursuant to the provisions of this subpart shall be paid to the United States as such interest is received by the sponsoring institution.

§ 61.22 Nondiscrimination.

Attention is called to the fact that funds paid to a sponsoring institution pursuant to § 61.11 in order to meet the expenses of the activities of a fellow are considered Federal financial assistance to such institution. The institution is thus subject in this respect to the prohibition against discrimination on the basis of race, color, or national origin imposed by Title VI, Civil Rights Act of 1964, and the implementing Regulation of the Department of Health and Human Services (45 CFR Part 80).

Subpart B—Service Fellowships

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216; secs. 207 and 208, 58 Stat. 685, as amended; 58 Stat. 686, as amended; 42 U.S.C. 209 and 210.

SOURCE: 31 FR 12098, Sept. 16, 1966, unless otherwise noted.

§ 61.30 Definitions.

As used in this part:

(a) "Service fellowship" is one which requires the performance of services, either full or part time, for the Public Health Service. A service fellow is an employee of the Public Health Service.

(b) "Surgeon General" means the Surgeon General of the U.S. Public Health Service or his delegate.

(c) "Continental United States" does not include Hawaii or Alaska.

§ 61.31 Applicability.

The regulations in this part apply to the establishment of service fellowships in the Public Health Service, the designation of persons to receive such fellowships, and the appointment of service fellows under authority of section 207(g) of the Public Health Service Act.

§ 61.32 Purpose of service fellowships.

Service fellowships in the Public Health Service are for the purpose of encouraging and promoting research, studies, and investigations related to health. Such fellowships may be provided to secure the services of talented scientists for a period of limited duration for health-related research, studies, and investigations where the nature of the work or the character of the individual's services render customary employing methods impracticable or less effective.

§ 61.33 Establishment of service fellowships.

All service fellowships shall be established by the Surgeon General. In establishing a service fellowship, or a series of service fellowships, the Surgeon General shall prescribe in writing the conditions (in addition to those provided in the regulations in this part) under which service fellows will be appointed and will hold their fellowships.

§ 61.34 Qualifications.

Scholastic and other qualifications shall be prescribed by the Surgeon General for each service fellowship, or series of service fellowships. Each individual appointed to a service fellowship shall (a) have presented satisfactory evidence of general suitability, including professional and personal fitness; (b) be free from any disease or disability that would interfere with his carrying out the purpose of the fellowship; and (c) possess any other qualifications as reasonably may be prescribed.

§ 61.35 Method of application.

Application for a service fellowship shall be made in accordance with procedures established by the Surgeon General.

§ 61.36 Selection and appointment of service fellows.

The Surgeon General shall (a) prescribe a suitable professional and personal fitness review and an examination of the applicant's qualifications; (b) designate in writing persons to receive service fellowships; and (c) establish procedures for the appointment of service fellows.

§ 61.37 Stipends, allowances, and benefits.

(a) *Stipends.* Service fellows shall be entitled to such stipend as is authorized by the Surgeon General for each service fellowship or series of service fellowships.

(b) *Travel and transportation allowances.* Under conditions prescribed by the Surgeon General, an individual appointed as a service fellow may be authorized travel allowances or transportation and per diem for himself, travel allowances or transportation for his immediate family, and transportation of household goods and personal effects, in conjunction with travel authorized by the Service (1) from place of residence, within or outside the continental United States, to first duty station, (2) for any change of duty station ordered by the Service during the term of the fellowship, and (3) from last duty station to the place of residence which he left to accept the fellowship, or to some other place at no greater cost to the Government. A service fellow shall be entitled to travel allowances or transportation and per diem while traveling on official business away from his permanent duty station during the term of the fellowship. Except as otherwise provided herein, a service fellow shall be entitled to travel and transportation allowances authorized in this part at the same rates as may be authorized by law and regulations for other civilian employees of the Public Health Service. If a service fellow dies during the term of a fellowship, and his place of residence which he left to accept the fellowship was outside the continental United States, the payment of expenses of preparing the remains for burial and transporting them to the place of residence for interment may be authorized. In the case of deceased service fellows whose place of resident was within the continental United States, payment of the expenses of preparing the remains and transporting them to the place of residence for interment may be authorized as provided for other civilian employees of the Public Health Service.

(c) *Benefits.* In addition to other benefits provided herein, service fellows shall be entitled to benefits as provided by law or regulation for other civilian employees of the Public Health Service.

(d) *Training.* Service fellows are eligible for training at Government expense on the same basis as other civilian employees.

§ 61.38 Duration of service fellowships.

Initial appointments to service fellowships may be made for varying periods not in excess of 2 years. Such appointments may be extended on a year-to-year basis in accordance with procedures and requirements established by the Surgeon General.

PART 62—NATIONAL HEALTH SERVICE CORPS SCHOLARSHIP AND LOAN REPAYMENT PROGRAMS

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AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 751 of the Public Health Service Act, 90 Stat. 2281 (42 U.S.C. 294t), unless otherwise noted.

SOURCE: 45 FR 55429, Aug. 20, 1980, unless otherwise noted.

Subpart A—National Health Service Corps Scholarship Program

§ 62.1 What is the scope and purpose of the National Health Service Corps scholarship program?

These regulations apply to the award of scholarships under the National Health Service Corps Scholarship Program authorized by section 751 of the Public Health Service Act (42 U.S.C. 294t) to students receiving academic training in medicine, osteopathy, dentistry, and other health professions. The purpose of this program is to assure an adequate supply of trained health professionals for the National Health Service Corps which is used by the Secretary to improve the delivery of health services in health manpower shortage areas.

§ 62.2 Definitions.

As used in this part:

"Acceptable level of academic standing" means the level at which a full-time student retains eligibility to continue in attendance in school under the school's standards and practices.

"Act" means the Public Health Service Act, as amended.

"Approved graduate training" means those programs of graduate training in medicine, osteopathy, dentistry or other health professions which (a) lead to eligibility for board certification or which provide other evidence of completion, and (b) have been approved by the appropriate health pro-

fessions body as determined by the Secretary.

"Full-time student" means an individual pursuing a course of study leading to a degree in medicine, osteopathy, dentistry or an equivalent credential for a particular health profession who is enrolled for a sufficient number of credit hours in any academic term to complete the course of study within not more than the number of academic terms normally required at the school. If an individual is enrolled in a school and is pursuing a course of study which is designed to be completed in more than 4 years, the individual will be considered a full-time student for only the last 4 years of the course of study.

"Health manpower shortage area" means the geographic area, the population group, the public or nonprofit private medical facility, or other public facility which has been determined by the Secretary to have a shortage of health manpower under section 332 of the Act and its implementing regulations (42 CFR Part 5).

"National of the United States" means a citizen of the United States or a person who, though not a citizen of the United States, owes permanent allegiance to the United States.

"Public Health and National Health Service Corps Scholarship Training Program", or "PH/NHSC Scholarship Training Program", means the program authorized by section 225 of the Act as in effect on September 30, 1977, and repealed on October 1, 1977.

"Scholarship Program" means the National Health Service Corps Scholarship Program authorized by section 751 of the Act (42 U.S.C. 294t).

"Scholarship Program participant" or "participant" means an individual whose application to the Scholarship Program has been approved and whose contract has been accepted and signed by the Secretary.

"School" means a school of medicine, osteopathy, dentistry, or other health profession which (a) provides training leading to a degree of doctor of medicine, doctor of osteopathy, doctor of dentistry, or an equivalent credential for a particular health profession, and (b) which is accredited by a body or bodies recognized for accreditation purposes by the Secretary of Education.

"School year" means all or part of the 12-month period from July 1 through June 30 during which an applicant is enrolled in a school as a full-time student.

"Service" means the United States Public Health Service.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State" means one of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

§ 62.3 Who is eligible to apply for a scholarship program award?

(a) To be eligible for a scholarship under this part an applicant must:

(1) Be accepted for enrollment, or be enrolled, as a full-time student in a school located in a State;

(2) Be pursuing a course of study or program offered by the school leading to a degree in medicine, osteopathy, dentistry, or an equivalent credential for a particular health profession;

(3) Be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the National Health Service Corps;

(4) Be a National of the United States; and

(5) Submit an application to participate in the Scholarship Program together with a signed contract as described in section 751(f) of the Act.

(b) Any applicant who owes an obligation for professional practice to a State or other entity under an agreement entered into before filing an application under this part is ineligible for an award unless a written statement satisfactory to the Secretary is submitted from the State or entity that (1) there is no potential conflict in fulfilling the service obligation to the State or entity and the Scholar-

ship Program, and that (2) the Scholarship Program service obligation will be served before the service obligation for professional practice owed to the State or entity.

(c) Any individual who receives a scholarship under the Indian Health Service Scholarship Program (section 757 of the Act) or the Scholarship Program for First-Year Students of Exceptional Financial Need (section 758 of the Act) is ineligible to participate in the Scholarship Program during the School year(s) for which the scholarships under sections 757 or 758 of the Act were awarded.

§ 62.4 To whom will scholarship program awards be available in addition to those individuals pursuing courses of study leading to degrees in medicine, osteopathy, or dentistry?

The Secretary will, from time-to-time, publish in the FEDERAL REGISTER a list of those health professions in addition to medicine, osteopathy, and dentistry for which the National Health Service Corps has need and for which support is available. The Secretary will also publish any other eligibility criteria, in addition to those in § 62.3, that may be required to assure that participants can be utilized during their periods of obligated service in a manner that will best meet the needs of the National Health Service Corps.

§ 62.5 How is application made for a scholarship program award?

Each individual desiring a scholarship under this part must submit an application (including a signed contract as required under section 751(f) of the Act) in the form and at the time prescribed by the Secretary.

§ 62.6 How will individuals be selected to participate in the scholarship program?

(a) *General.* In deciding which applications for participation in the Scholarship Program will be approved, the Secretary will place the applications into categories based upon the selection priorities described in paragraph (b) of this section. Except for continuation awards (see paragraph (e) of this section) the Secretary will then evaluate each applicant under paragraph (c) of this section.

(b) *Priorities.* (1) First priority will be given to individuals who have previously received a scholarship under the PH/NHSC Scholarship Training Program, a scholarship under this Scholarship Program, or a scholarship under section 758 of the Act, authorizing scholarships for first-year students of exceptional financial need. (2) Second priority will be given to applicants who are entering their first year of study.

(c) *Selection.* (1) In selecting participants, the Secretary will take into consideration those factors which he or she determines necessary to assure effective participation in the Scholarship Program. These factors may include, but not be limited to (i) work experience, (ii) community background, (iii) career goals, (iv) faculty recommendation, and (v) academic performance.

(2) Special consideration will be given to (i) medical and osteopathic students who indicate their intention to enter family practice, internal medicine, pediatrics, or osteopathic general practice residencies, (ii) dental students who indicate their intention to undertake general practice training following graduation or who plan no postgraduate training, and (iii) those individuals who indicate an intent to pursue other types of clinical practice or specialized training for which the National Health Service Corps has a particular need.

(d) *Duration of Scholarship award.* Subject to the availability of funds for the Scholarship Program, the Secretary will award a participant a scholarship under this part for a period of 1 school year.

(e) *Continuation awards.* Subject to the availability of funds for the Scholarship Program, the Secretary will award a continuation scholarship if (1) the participant requests a continuation, (2) the award will not extend the total period of Scholarship Program support beyond 4 years, and (3) the participant is eligible for continued participation in the Scholarship Program.

§ 62.7 What will an individual be awarded for participating in the scholarship program?

(a) *Amount of scholarship.* (1) A scholarship award for each school year will consist of (i) tuition, (ii) reasonable educational expenses, including required fees, books, supplies, and required educational equipment, and (iii) a monthly stipend for the 12-month period beginning with the first month of each school year in which the individual is a participant. For purposes of this section "required fees" means those fees which are charged by the school to all students pursuing a similar curriculum and "required educational equipment" means educational equipment which must be rented or purchased by all students pursuing a similar curriculum at that school.

(2) The Secretary may enter into a contract with the school in which the participant is enrolled for the direct payment of tuition and reasonable educational expenses in the participant's behalf.

(b) *Payment of scholarship: Leave-of-absence; repeated course work.* The Secretary will suspend scholarship payments to or on behalf of a participant if the school (1) approves a leave-of-absence for the participant for health, personal, or other reasons, or (2) requires the participant to repeat course work for which the Secretary has previously made scholarship payments under § 62.7. However, if the repeated course work does not delay the participant's graduation date, scholarship payments will continue except for any additional costs relating to the repeated course work. Any scholarship payments suspended under this paragraph will be resumed by the Secretary upon notification by the school that the participant has returned from the leave-of-absence or has completed the repeated course work and is pursuing as a full-time student the course of study for which the scholarship was awarded.

§ 62.8 What does an individual have to do in return for the scholarship program award?

(a) *General.* Except as provided in paragraphs (d), (f), and (g) of this section, each participant is obligated to (1) become a member of the National Health Service Corps employed as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a Federal civilian in the full-time clinical practice of the participant's profession and (2) serve in the health manpower shortage area to which the participant is assigned by the National Health Service Corps.

(b) *Beginning of service.* (1) The period of obligated service will begin when the Scholarship Program participant begins to provide services in the health manpower shortage area to which he or she is assigned by the Secretary. Except for those participants who receive a deferral under § 62.9 (a) or (b), this assignment will be made by the Secretary as soon as possible following: (i) the completion of the participant's course of study leading to a degree in medicine, osteopathy, dentistry, or an equivalent credential for a particular health profession, and (ii) appointment of the participant as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a civilian member of the National Health Service Corps.

(2) For purposes of this paragraph, "appointment" means only those appointments as Commissioned Officers in the Regular or Reserve Corps of the Service or as civilian members of the National Health Service Corps made specifically for the purpose of serving a participant's period of obligated service.

(c) *Duration of service.* Except as provided in § 62.14(b)(1), the period for which the Scholarship Program participant is obligated to serve is equal to 1 year for each school year for which the participant receives a scholarship award under this part, or 2 years, whichever is greater.

(d) *Service by detail.* If the Secretary determines that there is no need in a health manpower shortage area for a member of the profession in which the Scholarship Program participant is obligated to provide service, the Scholarship Program participant may be detailed to serve the period of obligated service as a full-time member of the profession for which the participant has been trained, in

any unit of the Department of Health and Human Services as the Secretary may determine.

(e) *Creditability of approved graduate training.* Except as provided in § 62.14(b)(2), no period of approved graduate training will be credited toward satisfying the period of obligated service incurred under the Scholarship Program.

(f) *Service under the National Research Service Award Program.* (1) A Scholarship Program participant who demonstrates exceptional promise for medical research may perform the period of obligated service owed under this section by participating in the National Research Service Award Program for individual postdoctoral fellows authorized under section 472 of the Act.

(2) Exceptional promise for medical research will be demonstrated if the participant applies for a National Research Service Award for individual postdoctoral fellows, is selected to participate in this research program, and accepts the offer of participation. A Scholarship Program participant in the National Research Service Award Program will receive credit toward satisfying the period of obligated service incurred under this section for any period of time he or she is engaged in activities which meet the service requirements of the National Research Service Award Program.

(3) If the time served under the National Research Service Award Program is less than the total period of obligated service owed under the Scholarship Program, the participant will serve the remainder of the Scholarship Program service obligation (i) in activities which meet the criteria for service under the National Research Service Award Program, as approved by the Secretary or (ii) as a member of the National Health Service Corps providing health services in the full-time clinical practice of his or her health profession. A participant who fails to begin or complete the service requirements under the National Research Service Award Program may be subject to the default penalty under § 62.10(c) of this part and the default penalties under the National Research Service Award Program.

(g) *Release from service obligation to engage in private practice.* The Secretary will release a participant from all or part of the service obligation if the participant applies for a release under section 753 of the Act and agrees in writing to engage for a period equal to the remaining period of the participant's service obligation in the full-time private clinical practice of the participant's health profession, under the requirements of section 753 of the Act.

§ 62.9 Under what circumstances can the period of obligated service be deferred to complete approved graduate training?

(a) *Requested deferment.* Upon the request of any participant receiving a degree from a school of medicine, osteopathy, or dentistry, veterinary medicine, optometry, podiatry or pharmacy, the Secretary will defer the beginning date of the obligated service to allow the participant to complete an approved graduate training program. The period of this deferment may not exceed (1) three years for any participant receiving a degree from a school of medicine, osteopathy or dentistry, or (2) one year for any participant recieving a degree from a school of veterinary medicine, optometry, podiatry or pharmacy. The Secretary may, however, extend this period of deferment if the Secretary determines that the extension is consistent with the needs of the National Health Service Corps.

(b) *Required deferment.* Each participant receiving a degree in medicine or osteopathy who does not intend to enter training which can be completed within the deferment period granted under paragraph (a) of this section must complete at least one year of approved graduate training before beginning the period of obligated service. This one year of training must be in (1) an allopathic flexible first-year program whose sponsorship includes approved residencies in family practice, internal medicine, pediatrics, or a categorical first-year program in family practice, internal medicine, or

pediatrics; (2) a rotating internship in osteopathic medicine; or (3) such other programs as the Secretary determines provides comparable experience. Any participant receiving a degree in medicine or osteopathy who fails to complete the one year of required training or an approved graduate training program for which a deferment was granted under paragraph (a) of this section will be subject to the default penalties of § 62.10(c).

(c) *Altering deferment.* Before altering the length or type of approved graduate training for which the period of obligated service was deferred under paragraphs (a) or (b) of this section, the participant must request and obtain the Secretary's approval of the alteration.

(d) *Additional terms of deferment.* The Secretary may prescribe additional terms and conditions for deferment under paragraphs (a), (b), and (c) of this section as necessary to carry out the purposes of the Scholarship Program.

(e) *Beginning of service after deferment.* Any participant whose period of obligated service has been deferred under paragraphs (a) or (b) of this section must begin the obligated service when the participant begins to provide health services in the health manpower shortage area to which he or she is assigned by the Secretary. This assignment will be made by the Secretary as soon as possible following (1) the completion of the requested or required graduate training for which the deferment was granted, and (2) appointment as a Commissioned Officer in the Regular or Reserve Corps of the Service or as a civilian member of the National Health Service Corps.

§ 62.10 What will happen if an individual does not comply with the terms and conditions of participating in the scholarship program?

(a) If a participant, other than one described in paragraph (b) of this section, fails to accept payment or instructs the school not to accept payment of the scholarship provided by the Secretary, the participant must, in addition to any service or other obligation incurred under the contract, pay to the United States the amount of $1,500 liquidated damages. Payment of this amount must be made within 30 days of the date on which the participant fails to accept payment of the scholarship award or instructs the school not to accept payment.

(b) When a participant fails to maintain an acceptable level of academic standing, is dismissed from the school for disciplinary reasons, or voluntarily terminates the course of study or program for which the scholarship was awarded before completing the course of study or program, the participant must, instead of performing any service obligation, pay to the United States an amount equal to all scholarship funds awarded under § 62.7. Payment of this amount must be made within 3 years of the date the participant becomes liable to make payment under this paragraph.

(c) If a participant fails to begin or complete the period of obligated service incurred under § 62.8, including failing to comply with the applicable terms and conditions of a deferment granted by the Secretary, the participant must pay to the United States an amount determined by the formula set forth in section 754(c) of the Act. Payment of this amount shall be made within 1 year of the date that the participant failed to begin or complete the period of obligated service, as determined by the Secretary.

§ 62.11 When can a scholarship program payment obligation be discharged in bankruptcy?

In accordance with section 754(d)(3) of the Act, any payment obligation incurred under § 62.10 may not be discharged in bankruptcy under Title XI of the United States Code until 5 years after the date on which the payment obligation is due.

§ 62.12 Under what circumstances can the service or payment obligation be canceled, waived or suspended?

(a) Any obligation of a participant for service or payment will be canceled upon the death of the participant.

(b)(1) A participation may seek a waiver or suspension of the service or payment obligations incurred under this part by written request to the

Secretary setting forth the bases, circumstances, and causes which support the requested action. The Secretary may approve a request for a suspension for a period of 1 year. A renewal of this suspension may also be granted.

(2) The Secretary may waive or suspend any service or payment obligation incurred by a participant whenever compliance by the participant (i) is impossible, or (ii) would involve extreme hardship to the participant and if enforcement of the service or payment obligation would be against equity and good conscience.

(c) Compliance by a participant with a service or payment obligation will be considered impossible if the Secretary determines, on the basis of information and documentation as may be required, that the participant suffers from a physical or mental disability resulting in the permanent inability of the participant to perform the service or other activities which would be necessary to comply with the obligation.

(d) In determining whether to waive or suspend any or all of the service or payment obligations of a participant as imposing an undue hardship and being against equity and good conscience, the Secretary, on the basis of information and documentation as may be required, will consider:

(1) The participant's present financial resources and obligations;

(2) The participant's estimated future financial resources and obligations; and

(3) The extent to which the participant has problems of a personal nature, such as physical or mental disability, terminal illness in the immediate family which so intrude on the participant's present and future ability to perform as to raise a presumption that the individual will be unable to perform the obligation incurred.

§ 62.13 What are the limitations on the receipt of concurrent benefits?

Under section 741(f) or 836(h) of the Act, the Secretary may agree to repay a portion of an individual's educational loans in return for the individual's agreement to practice his or her profession in an area in need of health manpower. However, a Scholarship Program participant may not enter into an agreement with the Secretary under section 741(f) or 836(h) of the Act, until either: (a) The participant has completed the service obligation under the Scholarship Program, (b) the Secretary has recovered from the participant an amount determined under § 62.10, or (c) any service or payment obligation has been waived under § 62.12. In no case shall a scholarship received under these regulations be considered an educational loan for the purposes of section 741(f) or 836(h) of the Act.

§ 62.14 What are the special provisions relating to recipients of awards under the PH/NHSC scholarship training program who will also receive awards under the scholarship program?

(a) Except as provided in paragraph (b) of this section, if a participant has previously received an award under the PH/NHSC Scholarship Training Program and also receives an award under the Scholarship Program, the terms and conditions of these regulations will apply to the participant's entire obligation incurred under both the PH/NHSC Scholarship Training Program and the Scholarship Program.

(b) If a participant has received an award under the PH/NHSC Scholarship Training Program and also receives an award under the Scholarship Program, the following conditions apply:

(1) *Period of obligated service—carry over.* The period of obligated service owed by the participant is equal to the total number of school years for which scholarship support was awarded under both the PH/NHSC Scholarship Training Program and the Scholarship Program without regard to either Program's minimum support requirement under 42 CFR 62.7(a) (1976) as adopted on May 22, 1974 (see 39 FR 17962), and under § 62.8(c) of this part.

(2) *Credit for internship and residency training.* (i) If a participant received a scholarship under the PH/NHSC Scholarship Training Program for any school year beginning before October 12, 1976, the participant will

receive credit toward satisfying the periods of obligated service incurred under the PH/NHSC Scholarship Training Program and under § 62.8 of this part for any periods of internship or residency training served in a Service or National Health Service Corps facility.

(ii) If a participant received a scholarship for the first time during the 1977-78 school year under the PH/NHSC Scholarship Training Program, the participant will only receive 1 year of credit toward satisfying the period of obligated service incurred under the PH/NHSC Scholarship Training Program for internship or residency training served in a Service or National Health Service Corps facility.

(3) *Default penalties.* The PH/NHSC Scholarship Training Program default penalty will apply to a participant who fails to begin or complete the active duty service obligation incurred under that Program, and the § 62.10 default penalties will apply to a participant who fails to begin or complete the service obligation incurred under § 62.8 of these regulations. In determining which default penalty to apply when an individual who has received a Scholarship award under both the PH/NHSC Scholarship Training Program and the Scholarship Program fails to begin or complete his service obligation, the service obligations will be considered to have been served in the order in which they were incurred.

Subpart B—National Health Service Corp Loan Repayment Program

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); Sec. 338B of the Public Health Service Act, 101 Stat. 992 (42 U.S.C. 2541-1).

SOURCE: 54 FR 13462, Apr. 3, 1989 (interim), unless otherwise noted.

§ 62.21 What is the scope and purpose of the National Health Service Corps Loan Repayment Program?

The regulations of this subpart apply to the award of health professions educational loan payments under the National Health Service Corps Loan Repayment Program authorized by section 338B of the Public Health Service Act (42 U.S.C. 2541-1). The purpose of the Program is to assure an adequate supply of trained health professionals for the National Health Service Corps. These professionals will be assigned by the Secretary to provide necessary health services to persons living in designated health manpower shortage areas.

§ 62.22 Definitions.

The definitions in § 62.2 of this part will apply for the purpose of this subpart, except for the definition of "approved graduate training." The following definitions will also apply for purposes of this subpart:

"Approved graduate training" means a program of graduate training in allopathic or osteopathic medicine, dentistry or other health profession which (a) leads to eligibility for board certification or which provides other evidence of completion, (b) has been approved by the appropriate health professions body as determined by the Secretary and (c) is in the specialty or type of training specified by the Program participant in the Loan Repayment Program Contract or, at the Program participant's request and at the Secretary's option, is in a specialty or area of training determined by the Secretary to be consistent with the needs of the National Health Service Corps.

"Commercial loans" means loans made by banks, credit unions, savings and loan associations, insurance companies, schools, and other financial or credit institutions which are subject to examination and supervision in their capacity as lenders by an agency of the United States or of the State in which the lender has its principal place of business.

"Educational expenses" means the costs of the health professions education, exclusive of the tuition, such as fees, books, supplies, and educational equipment and materials.

"Government loans" means loans which are made by Federal, State, county or city agencies which are authorized by law to make such loans.

"Living expenses" means the costs of room and board, transportation and commuting costs and other costs in-

curred during an individual's attendance at a health professions school.

"Loan Repayment Program" means the National Health Service Corps Loan Repayment Program authorized by section 338B of the Act (42 U.S.C. 2541-1).

"Loan Repayment Program Contract" means the agreement, which is signed by an applicant and the Secretary, for the Loan Repayment Program wherein the applicant agrees to accept repayment of health professions educational loans and to serve in accordance with the provisions of section 338B of the Act and this subpart for a prescribed period of obligated service.

"Medically underserved area" means "health manpower shortage area" as defined in section 62.2.

"Program participant" means an individual whose application to the Loan Repayment Program has been approved and whose contract has been accepted and signed by the Secretary.

"Qualifying loans" means government and commercial loans for actual costs paid for tuition, reasonable educational expenses, and reasonable living expenses relating to the obtainment of a degree in allopathic or osteopathic medicine, dentistry, or other health profession. Such loans must have documentation which is contemporaneous with the training received in a health professions school. If health professions educational loans are refinanced, the original documentation of the loan(s) will be required to be submitted to the Secretary to establish the contemporaneous nature of such loans.

"Reasonable educational and living expenses" means those educational and living expenses which are equal to or less than the sum of the school's estimated standard student budgets for educational and living expenses for the degree program and for the year(s) during which the Program participant is/was enrolled in the school. However, if the school attended by the Program participant does/did not have a standard student budget or if a Program participant requests repayment for educational and living expenses which are in excess of the standard student budgets described in the preceding sentence, the Program participant must submit documentation, as required by the Secretary, to substantiate the reasonableness of all educational and living expenses incurred by the Program participant. To the extent that the Secretary determines, upon review of the Program participant's documentation, that all or a portion of the educational and living expenses are reasonable, these expenses will qualify for repayment.

§ 62.23 How will individuals be selected to participate in the Loan Repayment Program?

(a) In determining which applications from eligible individuals for participation in the Loan Repayment Program will be accepted for consideration, the Secretary will apply the following criteria:

(1) The extent to which an individual's training is in a health profession or specialty determined by the Secretary to be needed by the National Health Service Corps;

(2) The individual's commitment to serve in medically underserved areas;

(3) The availability of the individual for service, with highest consideration being given to individuals who will be available for service at the earliest dates;

(4) The length of the individual's proposed service obligation, with greatest consideration being given to persons who agree to serve for longer periods of time; and

(5) The individual's academic standing, prior professional experience in a health manpower shortage area, board certification, residency achievements, peer recommendations, depth of past residency practice experience and other criteria related to professional competence or conduct.

(b) Among qualified applicants, the Secretary will give priority to applications from individuals whose health professions or specialties are most needed by the NHSC and who are, in the Secretary's judgement, most committed to practice in medically underserved areas.

(c) By notice published in the FEDERAL REGISTER from time to time, the Secretary will specify the professions

and specialties most needed by the National Health Service Corps.

§ 62.24 Who is eligible to apply for the Loan Repayment Program?

(a) To be eligible to participate in the Loan Repayment Program an individual must:

(1)(i) Be enrolled as a full-time student in the final year of a course of study or program approved by the Secretary which leads to a degree in allopathic or osteopathic medicine, dentistry or other health profession and which is offered by an accredited school in a State or (ii) be enrolled in an approved graduate training program in allopathic or osteopathic medicine or dentistry or other health profession in a State, or (iii) have a degree in allopathic or osteopathic medicine or dentistry or other health profession and have completed an approved graduate training program in a State (or received a waiver of the completion requirement under § 62.26(d) of this subpart) and have a current and valid license to practice such health profession in a State;

(2) Be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Public Health Service or be eligible for selection for civilian service in the National Health Service Corps;

(3) Submit an application to participate in the Loan Repayment Program; and

(4) Sign and submit to the Secretary, at the time of the submission of such application, a written contract agreeing to accept repayment of health professions educational loans and to serve (in accordance with this subpart) for the applicable period of obligated service in a health manpower shortage area as determined by the Secretary.

(b) Any individual who owes an obligation for health professional service to the Federal Government or a State or other entity under an agreement with such Federal, State or other entity is ineligible for the Loan Repayment Program unless such obligation will be completely satisfied prior to the beginning of service under this Program.

(c) Individuals in breach of a written contract entered into under section 338A of the Act and liable to the United States under section 338E(b) of the Act, in breach of a written contract entered into under section 225 of the Act (as in effect on September 30, 1977) and liable to the United States under section 225(f)(1) of the Act (as in effect on September 30, 1977) or in breach of any other obligation for health professional service to a Federal, State or local government entity are not eligible for participation in the Loan Repayment Program.

(Approved by Office of Management and Budget under control number 0915-0127)

§ 62.25 What does the Loan Repayment Program provide?

(a) *Loan repayment.* For each year of service the individual agrees to serve, with a minimum of 2 years of obligated service, the Secretary may pay: (1) Except as provided in paragraph (2), up to $20,000 per year of a Program participant's qualifying loans or (2) up to $25,000 per year for a Program participant's qualifying loans if the Program participant agrees to provide obligated service in the Indian Health Service or a health facility or program operated by a tribe or tribal organization under the Indian Self-Determination Act. Loan repayments by the Secretary in advance of service will be limited to one month or less. The Secretary may establish different levels of annual loan repayment to encourage Program participants to serve in a manner which is in the best interest of the Loan Repayment Program. No loan repayments will be made for any professional practice performed prior to the effective date of the Loan Repayment Program Contract. Once a loan repayment contract has been signed by both parties, the Secretary will obligate such funds as will be necessary to ensure that sufficient funds will be available to make loan repayments for the duration of the period of obligated service.

(b) *Site visit.* The Secretary may reimburse an individual for the actual and reasonable travel expenses associated with one trip from the individual's residence to a site for the purpose of evaluating such site for service

under the the Loan Repayment Program.

(c) *Tax liability payments.* The Secretary may, upon a Program participant's written request, make payments in a reasonable amount, as determined by the Secretary, to reimburse the Program participant for all or part of the increased Federal, State and local tax liability resulting from loan repayments received under the Loan Repayment Program. To maximize the Federal resources available for placing participants in HMSAs, supplementary payments for increased tax liability will only be made under unusual circumstances, and in no cases will these tax liability payments exceed 20% of the annual amounts of the loans being repaid. Program participants wishing to receive tax liability payments must submit their requests for such payments in a manner prescribed by the Secretary and must provide the Secretary with any documentation the Secretary determines is necessary to establish a Program participant's increased tax liability. The Secretary will determine, based on the availability of funds and such other factors as the Secretary determines, the amounts of any such payments that may be made.

(Information collection requirements contained in paragraph (c) were approved by Office of Management and Budget under control number 0915–0131)

§ 62.26 What does an individual have to do in return for loan repayments received under the Loan Repayment Program?

(a) A Program participant whose eligibility for the Loan Repayment Program is based on § 62.24(a)(1)(i) of this subpart must maintain full-time enrollment, at an acceptable level of academic standing, in that course of study until its completion. Upon completion of that course of study, a Program participant who received a degree in allopathic or osteopathic medicine must enter approved graduate training and a Program participant who received a degree in a health profession other than allopathic or osteopathic medicine may enter approved graduate training. Once a Program participant enters approved graduate training, he or she must also meet the requirements set forth in paragraphs (b) (1), (2), (3), and (4) of this section. If a Program participant who received a degree in a health profession other than allopathic or osteopathic medicine does not enter approved graduate training; service, in accordance with paragraph (e) of this section, must commence as soon as possible upon the Program participant's completion of the course of study leading to his or her health professions degree.

(b) A Program participant whose eligibility for the Loan Repayment Program is based on § 62.24(a)(1)(ii) of this subpart must: (1) Continue in his or her approved graduate training program at an acceptable level of academic standing; (2) provide the Secretary with annual documentation of continued participation in that approved graduate training program at an acceptable level of academic standing; (3) successfully complete that approved graduate training program; and (4) commence service, in accordance with paragraph (e) of this section, as soon as possible upon completion of approved graduate training.

(c) A Program participant whose eligibility for the Loan Repayment Program is based on § 62.24(a)(1)(iii) of this subpart must commence service, in accordance with paragraph (e) of this section, as soon as possible after the effective date of the Loan Repayment Program Contract.

(d) If a Program participant fails to complete approved graduate training, the Secretary may, on his or her own initiative or at the Program participant's request, waive, for good cause, the completion requirement. Good cause will be deemed to exist if the Secretary determines that the Program participant has sufficient health professions training to be utilized by and make a substantial contribution to the National Health Service Corps. If waiver of the completion requirement in paragraph (b) of this section is granted; service, in accordance with paragraph (e) of this section, must commence as soon as possible after the granting of the waiver.

(Information collection requirements contained in paragraph (b)(2) were approved by

Office of Management and Budget under control number 0915-0131).

(e) Except for Program participants who fail to complete their course of study leading to a health professions degree or who fail to complete approved graduate training and do not receive a waiver pursuant to paragraph (d) of this section, each program participant must: (1) Serve in a health manpower shortage area to which he or she is assigned by the Secretary as a member of the National Health Service Corps or serve pursuant to section 338D of the Act in a health manpower shortage area selected by the Secretary and (2) accept employment in a full-time clinical practice of the Program participant's profession, as (i) a commissioned officer in the Regular or Reserve Corps of the Public Health Service, (ii) a civilian member of the National Health Service Corps who is an employee of the United States, (iii) a member of the National Health Service Corps who is not an employee of the United States, or (iv) a private practitioner who is providing obligated service under the provisions of section 338D of the Act.

(f) The minimum length of obligated service is two years, or such longer period as the Program participant may agree to. The maximum length of obligated service is four years. If a Program participant agrees to an original contract of two or three years, such contract may be extended, subject to the availability of appropriated funding, for one year or two years (up to the four-year maximum). A one-year extension will not reactivate the statutory minimum requirement of two years of service.

§ 62.27 What will happen if an individual does not comply with the terms and conditions of participation in the Loan Repayment Program?

Program participants who default on their Loan Repayment Program Contracts will be subject to the applicable monetary payment provisions set forth at section 338E of the Act. Payment of any amount owed under section 338E of the Act shall be made within one year of the date the participant breached his or her Loan Repayment Contract, as determined by the Secretary.

§ 62.28 Under what circumstances can the service or payment obligation be canceled, waived or suspended?

A service or payment obligation under the Loan Repayment Program will be canceled or may be waived or suspended as provided in § 62.12 of this part of the regulations.

§ 62.29 Under what circumstances can the Loan Repayment Program obligation be discharged in bankruptcy?

Any payment obligation incurred under § 62.27 of this subpart may be released by a discharge in bankruptcy under Title 11 of the United States Code only if such discharge is granted after the expiration of the five-year period beginning on the first date that payment was required, and only if the bankruptcy court finds that nondischarge of the obligation would be unconscionable.

§ 62.30 What other regulations and statutes apply?

Other regulations and statutes which apply to this subpart include but are not limited to:

Debt Collection Act of 1982, Pub. L. 97-365 (5 U.S.C. 5514) including Section 4, Requirement that Applicant Furnish Taxpayer Identifying Number;

Fair Credit Reporting Act (15 U.S.C. 1681 et seq.);

Privacy Act of 1974 (5 U.S.C. 552a);

Section 215(a) of the Public Health Service Act, as amended (42 U.S.C. 216(a)), for PHS commissioned officers, and 5 U.S.C. 3301 for civil service employees both of which authorize verification of an individual's suitability for employment;

Privacy Act of 1974; Alteration of System of Records, 52 FR 21622-21627, June 8, 1987, regarding the collection, maintenance and allowable use of personal information requested from program applicants.

Subpart C—Grants for State Loan Repayment Programs

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 as amended, 63 Stat. 35 (42 U.S.C. 216); Sec. 338H of the Public Health Service Act, 101 Stat. 999 (42 U.S.C. 254q-1).

SOURCE: 54 FR 13464, Apr. 3, 1989 (interim), unless otherwise noted.

§ 62.51 What is the scope and purpose of the State Loan Repayment Program?

The regulations of this subpart apply to the award of grants authorized by section 338H of the Public Health Service Act (42 U.S.C. 254q-1) to support the establishment of State programs similar to the National Health Service Corps Loan Repayment Program authorized by section 338B of the Public Health Service Act (42 U.S.C. 2541-1). The purpose of this program is to improve the delivery of health services in medically underserved areas.

§ 62.52 Definitions.

In addition to the definitions in § 62.2 of this part, the following definitions will apply for purposes of this subpart:

The definitions of "Qualifying loans," "Commercial loans," "Government loans," "Educational expenses," and "Living expenses" as contained in § 62.22 of this part will apply for purposes of this subpart.

"Medically underserved area" means "health manpower shortage area" or an area which has been designated by a State pursuant to standards described in § 62.54(b)(1) of this subpart which the Secretary has deemed acceptable.

"State Loan Repayment Program" or "program" means a State loan repayment program authorized under section 338H (42 U.S.C. 254q-1) of the Act.

§ 62.53 Who is eligible for this program?

Any State is eligible to apply for a grant under this subpart.

§ 62.54 What must applications for the State Loan Repayment Program contain?

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary requires.

(b) The application shall contain a budget and narrative statement describing the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart. In addition, applications must include:

(1) A description of the State's standards for the designation of medically underserved areas, except that no description of designation standards will be required if the State elects to use health manpower shortage areas designated by the Secretary;

(2) An assessment of the need and demand in medically underserved areas within the State for health professions manpower with special emphasis on individuals whose training is in a health profession or specialty identified by the Secretary pursuant to § 62.23(b) of this Part. This assessment should include such demographic indicators of the need as the economic accessibility of health care services in the State as measured by poverty levels, the percentage of the service area population without health insurance, and the health status of the population as measured by the rates of infant mortality, low birth weight, geographic barriers and other indicators;

(3) A proposal for the placement of the health profession providers in medically underserved areas with the greatest need and demand in accordance with the need/demand assessment completed in compliance with paragraph (b)(2) of this section;

(4) Adequate assurances that sufficient current year State funds are available to cover the non-Federal share of State Loan Repayment Program costs;

(5) A description of how the program would meet the requirements of § 62.55 to demonstrate its similarity to the NHSC Loan Repayment program;

(6) A description of the source of, and plans for the use of, State matching funds;

(7) A description of how the program would be coordinated with Federal, State and other organized activities within the State which relate to health manpower services and resources;

(8) Identification of the State entity and key personnel who would administer the grant and a description of the qualifications and experience of that entity and its personnel concerning the State's health service delivery system and health manpower needs;

(9) A description of the State's plans for administration of the State's Loan Repayment Program which may include such provisions as annual levels of loan repayment to be made under the program, the number of health professionals to be funded, the frequency and timing of the loan repayments, program incentives for longer periods of service, procedures for monitoring the service of program participants and placing professionals in default for failure to complete their service obligation, penalties for default, provisions for waivers and suspensions, and a description of the contract/obligation process to be used by the State to obligate individuals receiving State loan repayments;

(10) A description of the State's need for Federal assistance in obtaining health professions resources and demonstrated inability to obtain such resources without Federal assistance;

(11) A description of how the State will accord special consideration to medically underserved areas with large minority populations; and

(12) The signature of an individual authorized to act for the State and to assume on behalf of the State the obligations imposed by the statute, the applicable regulations of this subpart and any additional conditions of the grant.

(Approved by Office of Management and Budget under control number 0915-0131)

§ 62.55 What State Program Elements are required to ensure similarity with the NHSC Loan Repayment Program?

A State Loan Repayment Program supported under this subpart must:

(a) Establish priorities for loan repayment applicants consistent with the provisions of § 62.23 of this Part;

(b) Contract only with a person who is (1) enrolled as a full-time student in the final year of a course of study or program in an accredited school in a State leading to a degree in allopathic or osteopathic medicine, dentistry or other health profession, or (2) enrolled in an accredited graduate training program in a State in allopathic or osteopathic medicine or dentistry or other health profession, or (3) a practitioner licensed by a State who has completed training in an accredited graduate training program in allopathic or osteopathic medicine, dentistry or other health profession;

(c) Provide that health professionals participating in a State Loan Repayment Program shall (1) serve for at least 2 years in a medically underserved area identified pursuant to § 62.54(b)(3) of this subpart in the full-time clinical practice of their profession, (2) charge for his or her professional services at the usual and customary rate prevailing in the area in which such services are provided, except that if a person is unable to pay such charge, such person shall be charged at a reduced rate or not charged any fee, (3) in providing health services, not discriminate against any person on the basis of such person's ability to pay for such services or because payment for the health services provided to such person will be made under the insurance program established under part A or B of Title XVIII of the Social Security Act or under a State plan for medical assistance approved under Title XIX of such Act, and (4) agree to accept an assignment under section 1842(b)(3)(B)(ii) of such Act for all services for which payment may be made under part B of Title XVIII of such Act and enter into an appropriate agreement with the State agency which administers the State plan for medical assistance under Title XIX of such Act to provide service to individuals entitled to medical assistance under the plan;

(d) Repay qualifying loans for participating health professionals;

(e) Provide that the loans of health professionals will be repaid on a periodic basis after the receipt of obligated services by such participant for such period; and

§ 62.56 How are the Federal grant funds and State matching funds to be used under this program?

The Federal share of any program shall not exceed 75 percent of the cost of the approved State program. The Federal share must be used to repay the qualifying loans of health professionals. No portion of the Federal share shall be used to pay for administrative costs of any State Loan Repayment Program. The State's share of the program may be used to repay qualifying loans of health professionals or administrative costs of the State's Loan Repayment Program, or a combination of both. All program administrative costs are to be borne by the State. No portion of the State's share of the program shall consist of Federal funds.

§ 62.57 How will States be selected to participate in this program?

Within the limits of funds available under Section 338H of the Act, the Secretary may award grants to State applicants whose proposed Loan Repayment Programs will, in his or her judgment, best promote the purposes of section 338H of the Act, taking into account, among other pertinent factors:

(a) The need of the State for health professions manpower;

(b) The number and type of providers the State proposes to support through this program;

(c) The acceptableness of the State's standards for the designation of medically underserved areas and the appropriateness of the proposed placements of obligated providers;

(d) The degree of similarity between the proposed State Loan Repayment Program and the National Health Service Corps Loan Repayment Program;

(e) The adequacy of the qualifications, the administrative and managerial ability and the experience of the State staff to administer and carry out the proposed project;

(f) The suitability of the applicant's approach and the degree to which the applicant's project is coordinated with Federal, State and other organized activities for meeting the State's health professions manpower needs and resources, including mechanisms for an ongoing evaluation of the program's activities;

(g) The source and plans for use of the State match (including the percentage of the State's match that is proposed to be used for loan repayments), the degree to which the State match exceeds 25% or has increased over time, and the amount of the match relative to the needs and resources of the States; and

(h) The extent to which special consideration will be extended to medically underserved areas with large minority populations.

§ 62.58 What other regulations apply?

Other regulations which apply to this subpart include but are not limited to:

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services-Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under part 80 of this title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 86—Nondiscrimination on the basis of sex in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

45 CFR Part 50—Policies of general applicability: Subpart D—Public Health Service grant appeals procedure

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 74—Administration of grants

45 CFR Part 75—Informal grant appeals procedures

40-158 O—90—2

45 CFR Part 92—Administrative Requirements for grants and cooperative agreements to State and local governments (effective October 1, 1988)

Subpart D—Special Repayment Program

AUTHORITY: Sec. 215 of the Public Health Service Act 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 204, Pub. L. 100-177, 101 Stat. 1000.

SOURCE: 54 FR 13466, Apr. 3, 1989 (interim), unless otherwise noted.

§ 62.71 What is the scope and purpose of the Special Repayment Program?

These regulations apply to the Special Repayment Program authorized under section 204 of Pub. L. 100-177, which provides a time-limited opportunity for persons who were, on November 1, 1987, in breach of a written contract under the Public Health and National Health Service Corps Scholarship Training Program or the National Health Service Corps Scholarship Program to satisfy their scholarship obligations through full-time clinical service. These regulations do not apply to any Public Health and National Health Service Corps Scholarship Training Program or National Health Service Corps Scholarship Program obligation which the Secretary has determined was completely satisfied through service or monetary payment prior to November 1, 1987. The purpose of this program is to supply trained health professionals for the National Health Service Corps, which is used by the Secretary to improve the delivery of health services in health manpower shortage areas.

§ 62.72 Definitions.

In addition to the definitions in § 62.2 of this Part, the following definitions will apply for purposes of this subpart:

"Prior approved service" means service performed prior to a Program participant's service start date under the Special Repayment Program (1) as a member of the National Health Service Corps pursuant to an assignment by the Secretary under section 333 of the Act, (2) under a written private practice option agreement signed by the Secretary pursuant to section 338D of the Act, or (3) in compliance with section 338C(e) of the Act.

"Eligible defaulters" means those individuals who, as of November 1, 1987, were: (1) in breach of a written contract entered into under section 338A of the Act and liable to the United States under section 338E(b) of the Act and/or in breach of a written contract entered into under section 225 of the Act (as in effect on September 30, 1977) and liable to the United States under section 225(f)(1) of the Act (as in effect on September 30, 1977), and (2) not already serving their obligations on December 1, 1987, under a judgment, forbearance agreement, or other written agreement to serve.

"HPOL" means the Health Manpower Shortage Area Placement Opportunity List described in section 204(b) of Pub. L. 100-177.

"Match" means that the Secretary has received documentation of (1) an offer of employment from a site which specifies at least the agreed upon salary and start date, and (2) the Program participant's acceptance of that offer. Provided, however, that if the Program participant would be self-employed, a "match" means that the Secretary has approved a program participant's private practice option application under section 338D(a) of the Act.

"Program participant" means an eligible defaulter whose contract under section 204 of Pub. L. 100-177 has been accepted and signed by the Secretary.

"SHPOL" means the Supplemental Health Manpower Shortage Area Placement Opportunity List described in section 204(d) of Pub. L. 100-177.

"Scholarship amount" means the sum of any amounts paid to, or on the behalf of, a scholarship recipient under the PH/NHSC Scholarship Training Program and/or the Scholarship Program.

"Special Repayment Program" or "Program" means the program authorized by section 204 of Pub. L. 100-177.

"Total debt" means the debt that would be owed by a Program participant under section 225(f)(1) of the Act, as in effect on September 30, 1977, and/or section 338E(b) of the

Act, as if no payments had been made on the debt.

§ 62.73 What are the procedures for participation in the Special Repayment Program?

(a) *Notice of eligibility for participation in the program.* On or before February 29, 1988, the Secretary will, subject to paragraph (h) of this section, send written notice to each eligible defaulter of the opportunity provided under this Program. The notice will be sent to the last known address of each eligible defaulter and will describe the special repayment options available under the Program.

(b) *Selection of repayment method.* On or before May 29, 1988, eligible defaulters who wish to participate in this Program must notify the Secretary of their intent to enter into a written contract to provide service in accordance with either section 204(b) or section 204(c) of Pub. L. 100-177. The election between section 204(b) and section 204(c) of Pub. L. 100-177 is binding on the eligible defaulters.

(c) *Service sites.* Eligible defaulters who enter into a written contract to serve under section 204 of Pub. L. 100-177 will receive a listing of approved sites appropriate to the service option they have selected. Program participants electing service under section 204(b) of Pub. L. 100-177 will receive a HPOL. Program participants electing service under section 204(c) of Pub. L. 100-177 will receive a SHPOL. The HPOL or SHPOL sent to the Program participant will be specific to the Program participant's profession and his or her specialty training, which is most needed by the National Health Service Corps. The Secretary is not required to identify placements for Program participants in a medical specialty for which the National Health Service Corps has no need.

(d) *Time frames for matching and commencing service.* If a Program participant electing to serve under section 204(b) of Pub. L. 100-177 chooses to serve at a remaining site on the 1988 HPOL, such participant must match to a site and must begin serving at the site by October 1, 1988. If a Program participant electing to serve under section 204(b) of Pub. L. 100-177 chooses to serve at a site on the 1989 HPOL, such participant must match to a HPOL site by February 15, 1989, and must begin service at the site by October 1, 1989. If a Program participant has elected to serve under section 204(c) of Pub. L. 100-177, such participant will have until May 15, 1989 to match to a SHPOL site and must begin service at that site by October 1, 1989.

(e) *Site visits.* The Program participant is responsible for the costs of any site visit(s) and any other contact with the site to obtain employment at the site.

(f) *Effect of failure to meet established time frames.* If a Program participant does not match to a site or begin service at that site within the time frames described in paragraph (d) of this section, his or her participation in the Special Repayment Program will be automatically ended and he or she will remain liable for the full scholarship debt(s), including accrued interest and/or damages.

(g) *Service.* Service must be performed in accordance with subpart II of Part D of Title III of the PHS Act. Service credit will begin after a Program participant has matched to a HPOL or SHPOL site and has commenced service at that site in accordance with subpart II of Part D of Title III of the PHS Act.

(h) *Secretary's exclusion authority.* The Secretary is authorized, at any time, to deny or terminate an individual's participation in the Program for reasons related to the individual's professional competence or conduct.

§ 62.74 How much credit will a Program participant receive for monetary repayments made, or for approved service performed, before beginning service under the Special Repayment Program?

(a) Prior approved service performed by a Program participant will be credited to the Program participant for the purpose of calculating the Program participant's remaining service obligation under this Program. Thus, the Program participant's remaining service obligation will be calculated by subtracting the number of days of the

Program participant's prior approved service from the number of days of the Program participant's original service obligation under the PH/NHSC Scholarship Training Program and/or the Scholarship Program. If a Program participant has made monetary payments, his or her remaining service obligation will be reduced by converting the monetary payments into days of service credit as set forth in paragraph (b) or (c) of this section, whichever is applicable.

(b) Program participants who elect to serve pursuant to sections 204(b) and 204(c)(2) of Pub. L. 100-177, will not receive a refund of any amounts previously paid but will receive service credit for those payments as follows:

(1) The number of days of service credit will be calculated by dividing the total amount paid by the Program participant prior to the Program participant's service start date by the total debt as of the service start date and multiplying the result of that division by the number of days of the participant's remaining service obligation (as determined by the formula set forth in the second sentence of paragraph (a) of this section).

(2) If the Program participant defaults on a contract under this Program, prior monetary payments will not be credited to service but will be applied to the monetary debt owed by the Program participant.

(c) Program participants who elect to serve under section 204(c)(1) of Pub. L. 100-177 must pay an amount equal to the scholarship amount. Any amounts paid by the Program participant prior to or after entry into the Program, in accordance with § 62.76 of this subpart, will be used to reduce the Program participant's financial obligation incurred under section 204(c)(1) of Pub. L. 100-177. In some cases, the amounts paid before or after entry into the Program will exceed the scholarship amount. These payments in excess of the scholarship amount will be converted into days of service credit under the formula set forth in paragraph (b)(1) of this section. If a Program participant defaults on a contract under this option, the monies paid in excess of the scholarship amount will not be credited to service but will be credited toward the monetary debt owed by the Program participant under section 338E(b) of the Act or section 225(f)(1) of the Act, as in effect on September 30, 1977. The scholarship amount paid upon entering this option will be forfeited.

§ 62.75 Will individuals serving under the Special Repayment Program receive credit for partial service?

(a) With respect to obligations under the Scholarship Program, a credit will be allowed for partial service under the Special Repayment Program and will result in a reduction of the Program participant's financial obligation in accordance with the following formula:

$$A = 3\,0\ \frac{[t-(s+1/2r)]}{t}$$

In which:

'A' is the amount the United States is entitled to recover,

'0' is the sum of the amounts paid to or on behalf of the Program participant under the Scholarship Program and the interest on such amounts which would be payable if, at the time the amounts were paid, they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States.

't' is the total number of months in the Program participant's period of obligated service under the Program including any additional months of service incurred pursuant to section 204(c)(1) of Pub. L. 100-177

's' is the number of months of prior approved service performed by the Program participant before commencing service under this Program, and

'r' is the number of months of service performed by the Program participant in compliance with this Program.

However, where a judgment has been entered against a Program participant, the formula will be revised such that "30" equals the amount of the judgment representing the Program participant's liability under the Scholar-

ship Program, including any accrued postjudgment interest and excluding any monetary payments on the judgment which may have been made by the Program participant and "s" equals the number of months of prior approved service performed by the Program participant after the entry of the judgment but before commencing service under this Program.

(b) With respect to obligations under the PH/NHSC Scholarship Training Program, if a Program participant fails to complete the period of obligated service under the Program (including any additional months of service incurred pursuant to section 204(c)(1) of Pub. L. 100-177), no credit for partial service under this Program will be allowed.

(c) Where participants have obligations under both the Scholarship Program and the PH/NHSC Scholarship Training Program, credit for service will be applied against the scholarship obligations in the order in which they were incurred.

§ 62.76 How will amounts of money due under the option under section 204(c)(1) of Pub. L. 100-177 be required to be repaid?

Program participants who elect to serve under section 204(c)(1) of Pub. L. 100-177 will be required to pay the full scholarship amount at least 60 days prior to the service start date specified in the documentation submitted to the Secretary.

PART 63—NATIONAL INSTITUTES OF HEALTH AND NATIONAL LIBRARY OF MEDICINE TRAINEESHIPS

Sec.
63.1 Nature and purpose of traineeships.
63.2 Minimum qualifications.
63.3 Award of traineeships.
63.4 Benefits.
63.5 Terms and conditions of award.
63.6 Termination of traineeships.
63.7 Appropriate Institute.

AUTHORITY: Sec. 215, 58 Stat. 690, secs. 301, 402, 403, 58 Stat. 691, 707, sec. 303, 60 Stat. 423, secs. 412, 422, 62 Stat. 464, 598, sec. 433, 64 Stat. 444; 42 U.S.C. 216, 241, 282, 283, 242a, 287a, 288a, 289c.

SOURCE: 21 FR 9868, Dec. 12, 1956, unless otherwise noted.

§ 63.1 Nature and purpose of traineeships.

(a) A National Institutes of Health traineeship is an award of funds to an individual for his subsistence during a period in which he is acquiring advanced training in the diagnosis, prevention or treatment of diseases of public health significance. The purpose of such traineeships is to make available in the United States for the community effort against such diseases an increased number of persons having special competence in such diagnosis, prevention or treatment.

(b) A National Library of Medicine Traineeship is an award of funds to an individual for his subsistence and other expenses during a period in which he is acquiring advanced training in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of communication of health sciences information.

[21 FR 9868, Dec. 12, 1956, as amended at 31 FR 9505, July 13, 1966]

§ 63.2 Minimum qualifications.

Minimum qualifications for any traineeship shall be established by the Director of the appropriate Institute with the approval of the Surgeon General, and shall be uniformly applicable to all applicants in each traineeship program of such Institute. Such minimum qualifications may include requirements as to age, physical or mental condition, academic degrees, professional or other training or experience and such other factors as may be necessary to the fulfillment of the purpose of the traineeship. To the extent the Surgeon General finds it not inconsistent with such fulfillment, however, he may in individual cases waive compliance with any minimum qualification so established if he determines that the applicant has substantially equivalent qualifications or has such special training, experience or opportunity for service as make an award particularly appropriate.

§ 63.3 Award of traineeships.

Subject to the regulations of this part, the Surgeon General or his delegate may award traineeships to those qualified applicants who are best able

in his judgment to carry out the purpose of the traineeships. Such awards may be made in the name of the appropriate Institute.

§ 63.4 Benefits.

Each individual awarded a traineeship shall be entitled to the following benefits:

(a) A stipend fixed in amount by the Surgeon General and payable with respect to a period of one year or such other period, including extensions or renewals, as may be specified by the Surgeon General or his delegate in making awards.

(b) An additional allowance, if requested by the trainee and approved in advance by the Surgeon General or his delegate, for travel, per diem and transportation not exceeding such amounts as may be prescribed by the Surgeon General.

§ 63.5 Terms and conditions of award.

All traineeship awards shall be subject to the following terms and conditions:

(a) Training must be carried out at an institution found by the Director of the appropriate Institute to provide a well-rounded course of instruction in the particular field in which the traineeship is awarded. A change in the training institution may be made only with the approval of such Director.

(b) No traineeship may be utilized to compensate, nor awarded as consideration, for personal services or employment of the trainee for the United States or for any other person.

(c) No payment shall be made to any citizen or noncitizen national of the United States receiving an award under the regulations in this part unless such citizen or noncitizen national has taken, subscribed to, and filed with the Public Health Service a written oath or affirmation in the following terms: "I do solemnly swear (or affirm) that I bear true faith and allegiance to the United States of America and will support and defend the Constitution and laws of the United States against all its enemies, foreign and domestic."

(d) Additional conditions consistent with the regulations in this part may be established by the Surgeon General or his delegate to the extent he finds them necessary to fulfill the purpose of the traineeship.

(e) A noncitizen national of the United States is a person, who, though not a citizen of the United States, owes permanent allegiance to the United States.

(f) Payments made under awards pursuant to § 63.1(b) may be made to the trainee or the sponsoring institution. Except as may be otherwise prescribed by the Surgeon General, payments shall be made in advance or by way of reimbursement and in monthly installments.

[21 FR 9868, Dec. 12, 1956, as amended at 30 FR 6072, Apr. 29, 1965; 31 FR 9505, July 13, 1966]

§ 63.6 Termination of traineeships.

The Surgeon General or his delegate may terminate a traineeship at any time upon request of the trainee, and shall terminate any traineeship prior to the date it would otherwise expire upon a determination, made or approved by the Surgeon General, either that the trainee's performance is unsatisfactory or that he is unfit or unable to carry out the purpose of the traineeship.

§ 63.7 Appropriate Institute.

As used in this part "appropriate Institute" shall mean the National Cancer Institute for traineeships in the field of cancer, the National Institute of Mental Health for traineeships in the field of mental disorders, the National Heart Institute for traineeships in the field of cardiovascular diseases, the National Institute of Dental Research for traineeships in the field of dental diseases and conditions, the National Institute for Allergy and Infectious Diseases for traineeships in the field of allergy and infectious diseases, the National Institute of Arthritis and Metabolic Diseases for traineeship in the field of arthritis, rheumatism and metabolic disease, the National Institute of Neurological Diseases and Blindness for traineeships in the field of epilepsy, cerebral palsy, multiple sclerosis, other neurological and sensory disorders, and any other institute hereafter established by the

Surgeon General under section 431 of the Public Health Service Act, as amended, for traineeships in the field of those diseases constituting the responsibility of such institute. "Appropriate Institute" shall also mean, with respect to awards pursuant to § 63.1(b), the National Library of Medicine.

[21 FR 9868, Dec. 12, 1956, as amended at 31 FR 9505, July 13, 1966]

PART 64—NATIONAL INSTITUTES OF HEALTH AND NATIONAL LIBRARY OF MEDICINE TRAINING GRANTS

Sec.

64.1 Nature and purpose of training grants.
64.2 Application requirements.
64.3 Award of training grants.
64.4 Conditions to awards; general.
64.5 Additional conditions; institutional expenses.
64.6 Additional conditions; stipends.
64.7 Payments; repayment of unexpended balances; unauthorized expenditures.
64.8 Appropriate Institute.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216; sec. 433, 64 Stat. 444; 42 U.S.C. 289c.

SOURCE: 21 FR 9869, Dec. 12, 1956, unless otherwise noted.

§ 64.1 Nature and purpose of training grants.

(a) A National Institutes of Health training grant is an award of funds to a qualified educational or training institution, the objective of such grants being to make available for the community effort against diseases of public health significance an increased number of facilities providing adequate training and instruction, and an increased number of persons having special competence, in matters relating to the diagnosis, prevention and treatment of such diseases. Such a grant may have one or both of the following purposes:

(1) To defray the expenses of the institution in providing training and instruction in matters relating to the diagnosis, prevention or treatment of diseases within the responsibility of the appropriate Institute.

(2) To enable the institution to pay stipends and allowances to individuals with respect to a period in which they receive under the direction of such institution training and instruction in matters relating to such diagnosis, prevention or treatment.

(b) A National Library of Medicine training grant is an award of funds to a qualified educational or training institution, the objective of such a grant being to make available an increased number of facilities providing adequate training and instruction, and an increased number of persons having special competence in medical library service and science and in the field of communication of information pertaining to sciences relating to health. Such a grant may have one or both of the following purposes:

(1) To defray the expenses of the institution in providing training and instruction in medical library service and science and in communication of health sciences.

(2) To enable the institution to pay stipends and allowances to individuals during the periods in which they receive, under the direction of such institution, training and instruction in such science and communication.

[21 FR 9869, Dec. 12, 1956, as amended at 31 FR 9505, July 13, 1966]

§ 64.2 Application requirements.

Training grants shall be awarded only to those public or other nonprofit institutions which file applications in such form and manner as may be prescribed by the Surgeon General. Such applications shall set forth, in addition to any other pertinent information that may be required, the name and qualifications of the program director who will be responsible for the training and instruction and the following information depending upon the purposes for which the grant is requested:

(a) *Institutional expenses.* Applications which include a request for funds to meet institutional expenses shall set forth the nature and duration of the training and instruction program with respect to which the application is filed, the total amount requested and the purposes for which the funds will be used, stating separately the amounts requested for personal services and the amounts re-

quested for equipment, supplies or other non-personal expenses.

(b) *Stipends.* Applications which include a request for funds to enable the institution to make payments to individuals receiving training shall state the nature and duration of the training and instruction to be provided, and the applicant shall also furnish information concerning the minimum qualifications required of the individuals to be trained or instructed, the rate of stipend and allowances to be paid, and the total amount requested for these purposes.

§ 64.3 Award of training grants.

Subject to the regulations in this part, the Surgeon General may award training grants to such eligible public or other nonprofit institutions as are best able in his judgment to carry out the purpose of such grants. Such grants may be made in the name of the appropriate Institute, but no such grant may be made unless it has been recommended by the national advisory council for such Institute.

§ 64.4 Conditions to awards; general.

All training grants awarded under the authority of this part shall be subject to the following conditions:

(a) No essential or significant reduction in the quality or duration of the training and instruction shall be made by the grantee institution unless approved by the Director of the appropriate Institute upon recommendation by the national advisory council for such Institute.

(b) No substitution may be made for the program director named in the application as responsible for the training and instruction unless the substitute director is found by the Director of the appropriate Institute to have substantially equivalent qualifications with respect to providing the training and instruction for which the grant was awarded.

(c) The fiscal and other records of the institution that relate to the training and instruction for which the grant was awarded shall be available for audit or other reasonable inspection by representatives of the Public Health Service.

(d) Additional conditions consistent with the regulations in this part may be imposed by the Director of the appropriate Institute prior to the award of any training grant if he determines that such conditions are necessary to carry out the purposes of such grant.

§ 64.5 Additional conditions; institutional expenses.

Amounts awarded to enable institutions to defray the expenses of providing training and instruction shall be subject to the following conditions in addition to those set forth in § 64.4:

(a) The funds awarded may be expended solely for the training and instruction program set forth in the application for the grant and for such other related purposes as are determined by the Director of the appropriate Institute to be necessary to such program.

(b) No part of the funds awarded may be used for the purchase of land or for the construction of buildings.

(c) No funds may be used for indirect costs or overhead in excess of the rate generally applicable to training grants at the time of the award.

§ 64.6 Additional conditions; stipends.

Amounts awarded to enable institutions to pay stipends and allowances to individuals receiving advanced training shall be subject to the following conditions in addition to those set forth in § 64.4:

(a) No part of the funds requested for stipend payments may be used for any other purpose unless approved by the Director of the appropriate Institute.

(b) No part of the amount awarded may be used as remuneration for employment or for the performance of personal services by the individuals receiving the training and instruction.

(c) No amount may be paid by the institution to any individual who, by reason of age, physical or mental condition, or other relevant factor would not, in the reasonable judgment of the institution, be able to make use of the training and instruction.

(d) No amount may be paid by the institution to an individual who does not meet the minimum qualifications

for the training and instruction as established by the institution, nor shall any amount be paid to any individual who has failed to demonstrate satisfactory participation in the training in accordance with the usual standards and procedures of the institution.

§ 64.7 Payments; repayment of unexpended balances; unauthorized expenditures.

(a) Payments to an institution of amounts awarded under the regulations of this part may be made in advance and shall be in such amounts as are necessary in the judgment of the Director of the appropriate Institute to carry out the training program as set forth in the approved application of the institution or in any extension or renewal thereof. Any funds paid and found in the judgment of such Director to be not necessary for such purposes shall be returned to the United States.

(b) In the event any part of the amount paid an institution is found by the Director of the appropriate Institute to have been expended by the institution for purposes or by any methods contrary to the regulations of this part or contrary to any condition to the award, then such institution, upon being notified of such finding and in addition to any other requirement, shall pay an equal amount to the United States.

(c) Whenever the Director of the appropriate Institute shall find that the application or other documents on the basis of which a grant was awarded under the regulations of this part contain a material misrepresentation by or on behalf of the institution, or whenever he shall find that the institution has not, after a reasonable opportunity, corrected a substantial failure to comply with these regulations or with any condition to the award, he shall promptly notify the institution of such finding. Upon receipt of such notice, such institution, in addition to any other action required by law or these regulations, shall return to the United States immediately all funds not actually expended at the time of its receipt of such notice. If requested by the institution, any such findings may be reviewed by the Surgeon General whose decision shall be final.

§ 64.8 Appropriate Institute.

As used in this part "appropriate Institute" shall mean the National Cancer Institute for training grants in the field of cancer; the National Institute of Mental Health for training grants in the field of mental disorders; the National Heart Institute for training grants in the cardiovascular and related fields; the National Institute of Dental Research for training grants in the field of dental diseases and conditions; the National Institute of Allergy and Infectious Diseases for training grants in the field of allergy and infectious diseases; the National Institute of Arthritis and Metabolic Diseases for training grants in the field of arthritis and metabolic diseases; the National Institute of Neurological Diseases and Blindness for training grants in the field of neurological diseases, blindness, and other sensory disorders; and any other Institute established by the Surgeon General under section 431 of the Public Health Service Act, as amended, for training grants in the field of those diseases constituting the responsibility of such Institute: "Appropriate Institute" shall also mean, with respect to National Library of Medicine training grants, the National Library of Medicine.

[21 FR 9869, Dec. 12, 1956, as amended at 31 FR 9505, July 13, 1966]

PART 64a—OBLIGATED SERVICE FOR MENTAL HEALTH TRAINEESHIPS

Sec.

64a.101 Purpose.
64a.102 To whom do these regulations apply?
64a.103 Definitions.
64a.104 What requirements are imposed upon grantees?
64a.105 What are the conditions of obligated service?

AUTHORITY: Sec. 803, Pub. L. 96-398, 94 Stat. 1607-1608 (42 U.S.C. 242a).

SOURCE: 46 FR 39979, Aug. 5, 1981, unless otherwise noted.

§ 64a.101 Purpose.

This part establishes requirements to implement the service payback obligation of individuals who receive clinical traineeships in pyschology, psychiatry, social work, or nursing (that are not of limited duration or experimental nature) under section 303 of the Public Health Service Act.

§ 64a.102 To whom do these regulations apply?

This part applies to any institution which receives a training grant under section 303 of the Public Health Service Act and to any individual who receives a stipend or other trainee allowances under such a grant for any period beginning on or after July 1, 1981, for clincial training in the field of psychology, psychiatry, nursing, or social work, except for training that is of a limited duration or experimental nature.

§ 64a.103 Definitions.

As used in this part:

"Act" means the Public Health Service Act as amended by Pub. L. 96-398.

"Clinical traineeship" means a stipend or other trainee allowances provided to an individual for clinical training in psychology, psychiatry, nursing, or social work, except for training that is of a limited duration or experimental nature, under a training grant authorized by section 303 of the Act.

"Community Mental Health Centers Act" means the Community Mental Health Centers Act (42 U.S.C. 2689 *et seq.*) other than Part D thereof.

"Experimental nature" refers to the training of undergraduates; the training of individuals in disciplines other than psychology, psychiatry, nursing, or social work; and any other training which the Secretary specifically designates as experimental in the notice of award for a training grant under section 303 of the Act.

"Limited duration" means a period that is equal to or less than 180 days, computed cumulatively over a two year period which begins on the first day of the clinical traineeship.

"Mental Health Systems Act" means the Mental Health Systems Act (42 U.S.C. 9401 *et seq.*).

"Nonprofit private entity" means an agency, organization, institution or other entity which may not lawfully hold or use any part of its net earnings to the benefit of any private shareholder or individual and which does not hold or use its net earnings for that purpose.

"Other trainee allowances" means financial assistance for those costs not covered by stipends, such as tuition, fees, and trainee travel, which are directly associated with and necessary to the training of individuals receiving stipends and are incurred within the period of training.

"Secretary" means the Secretary of Health and Human Services or other official of the Department to whom the authority involved has been delegated.

"Stipend" means financial assistance to an individual that is intended to help meet that individual's subsistence expenses during training.

§ 64a.104 What requirements are imposed upon grantees?

Recipients of training grants under section 303 of the Act that provide a clinical traineeship to any individual must:

(a) Give each such individual written notice of the service payback and recovery requirements of this part at the time the individual becomes a candidate for the traineeship;

(b) Before awarding a clinical traineeship, conduct an entrance interview with the individual in order to explain and emphasize the service obligation the individual is incurring, obtain the individual's written assurance that he or she will satisfy the requirements of § 64a.105, and document, in accordance with paragraph (d) of this section, the entrance interview on the form containing the individual's written assurance.

(c) At the time of termination of the clinical traineeship,

(1) Notify the Secretary in writing of the date on which the individual's traineeship is terminated;

(2) Conduct an exit interview with the individual to remind the trainee of the service obligation, to fully explain the consequences that will incur

should the trainee fail to satisfy the obligation, and, to tell the individual that the Secretary has been notified of the date of termination of the traineeship; and

(3) Document, in accordance with paragraph (d) of this section, the exit interview on the form notifying the Secretary of the termination of the traineeship.

(d) Document the entrance and exit interviews with at least the following information: The date of the interview, the names of the participants involved in the interview, and a statement that the interview included an explanation to the individual of the service payback requirement and the consequences of failing to fulfill the service payback requirement.

(Approved by the Office of Budget and Management under control number 0930-0120)

[46 FR 39979, Aug. 5, 1981, as amended at 52 FR 18359, May 15, 1987]

§ 64a.105 What are the conditions of obligated service?

In order to receive a clinical traineeship an individual must comply with the following conditions:

(a) *Written assurance.* Prior to the award of a clinical traineeship, the individual must sign a written assurance (in such form and manner as the Secretary prescribes) that he or she will satisfy the requirements of this section.

(b) *Commencement and crediting of service.* (1) An individual must start the obligated service within twenty-four months after termination of the clinical traineeship and carry out the service on a continuous basis unless, as specified in paragraph (e) of this section, the individual has requested and had approved, respectively, an extension of the time for beginning the service, or a break in service.

(2) Following termination of the traineeship, the individual must annually provide (in such form and manner as the Secretary prescribes) a written report describing those previous years' activities which are related to service that fulfills the payback obligation. The Secretary will review this report and credit all service performed in those categories specified in paragraph (d) of this section toward the individual's payback obligation, except any service which is performed:

(i) Before termination of the individual's clinical traineeship; and

(ii) As part of any activity, such as course work, preparation of a dissertation or thesis, or practicum, which is needed to complete the training for which the individual received the traineeship.

(c) *Duration of obligation.* The period of service payback must equal the period of support under the clinical traineeship on a month for month basis.

(d) *Performance of the obligated service*—(1) *General requirements.* The obligated service must consist of the provision of service for which the individual was trained (in the training program for which the clinical traineeship was received) and must be performed on a full-time basis (not less than 30 hours per week averaged over the obligated service period).

(2) *Preferred service.* Except as provided under paragraph (d)(3) of this section, the individual must provide the obligated service in:

(i) A public inpatient mental institution;

(ii) Any entity which is receiving or has received a grant under the Mental Health Systems Act or the Community Mental Health Centers Act;

(iii) A psychiatric manpower shortage area designated by the Secretary under section 332 of the Public Health Service Act and 42 CFR Part 5;

(iv) Any public or private nonprofit entity or in any nursing home (whether public, private nonprofit, or for profit) in which 50 percent or more of those served are within one or more of the following groups: Racial or ethnic minorities (American Indian or Alaskan Native, Asian or Pacific Islander, Black, Hispanic), chronically mentally ill, mentally retarded, criminal or delinquent populations, rape victims, physically handicapped, abusers of alcohol, or persons addicted to drugs or other substances, children and adolescents, the elderly, poverty populations, migrants, members of the armed forces (or veterans if seen in a Federal facility), residents of areas other than those defined as urbanized by the De-

partment of Commerce, or any other special populations, such as groups of refugees or disaster victims, which are specifically designated by the Secretary for this purpose.

(3) *Alternate service.* If the individual obtains the written approval of the Secretary, the individual may fulfill his or her obligation by:

(i) Serving in any public or private nonprofit entity or in any nursing home (whether public, private nonprofit, or for profit) in which not less than 25 percent of those served are within one or more of the underserved population groups listed in paragraph (d)(2)(iv) of this section. The individual must demonstrate a service commitment of more than 50 percent of his or her time to the targeted populations.

(ii) Teaching, conducting research, or conducting evaluation directed at improving alcohol, drug abuse or mental health services to one or more of the priority population groups listed in paragraph (d)(2)(iv) of this section, or working in a position which fosters the closer collaboration of health and alcohol, drug abuse or mental health services.

(iii) Providing in a public or private nonprofit entity consultation, training and education, liaison, community support or other professional services for which the individual was trained when the individual's work is directed toward improving alcohol, drug abuse or mental health services to the priority populations listed in paragraph (d)(2)(iv) of this section.

(e) *Conditions for deferral or break in service, waiver, or cancellation.* (1) Upon receipt of a written request showing good cause therefor by the individual having a payback obligation, the Secretary may:

(i) Extend the period for beginning the obligated service (24 months after termination of the clinical traineeship), permit breaks in the required continuous service or extend the period for repayment under paragraph (g)(2) of this section, if it is determined that:

(A) An extension or break in service is necessary for the completion of training;

(B) Performance of the obligation must be delayed because a temporary disability makes present performance impossible; or

(C) Performance of the obligation must be delayed because present performance would involve a substantial hardship and failure to extend the period would be against equity and good conscience.

(ii) Waive, in whole or in part, the service payback and recovery requirements of this section if it is determined that fulfillment would be impossible because the individual is permanently and totally disabled.

(iii) In making determinations under § 64a.105(e)(1)(i)(C), the Secretary will take into consideration the following factors:

(A) The individual's present financial resources and obligations;

(B) The individual's estimated future financial resources and obligations;

(C) The reasons for the individual's failure to complete the requirements within the prescribed period, such as problems of a personal nature;

(D) The unavailability of employment opportunities appropriate to the individual's education and training; and

(E) Any other extenuating circumstances.

(2) Upon receipt of written notice giving evidence of a conflicting obligation under section 752 or 753 of the Act or of an election to fulfill an obligation under section 472 of the Act prior to an obligation under this section, the Secretary will extend the period for beginning service (24 months after termination of the clinical traineeship), permit breaks in the required continuous service or extend the period for repayment under paragraph (g)(1), as appropriate.

(3) The service payback and recovery obligations of an individual will be cancelled upon the submission to the Secretary of a certificate of that individual's death or other evidence which the Secretary determines to be satisfactory.

(f) *Conflicting or multiple payback obligations.* In any case where the individual has, in addition to a payback obligation incurred under this section,

an obligation to perform service under section 752 or 753 of the Act (because of receipt of a National Health Service Corps scholarship) or under section 472 of the Act (because of receipt of a National Research Service Award), or both, performance of the same activity may not be counted toward more than one of these obligations. In determining the order in which obligations must be fulfilled, obligations under section 752 or 753 take precedence over obligations incurred under this section. However, with respect to obligations under this section and 472, the individual may elect which obligation to fulfill first. Any individual who has an obligation under section 752 or 753 or makes an election to fulfill an obligation under section 472 prior to an obligation under this section, must give written notice to the Secretary as provided by paragraph (e)(3) of this section.

(g) *Recovery for failure to perform obligated service.* (1) If an individual fails to begin or complete the obligated service in accordance with the requirements of paragraphs (a) through (f) of this section, that individual is obligated to repay the United States an amount equal to three times the cost of the award (including stipends and other trainee allowances) plus interest on that amount calculated for the total period since the trainee failed to perform the obligated service at the rate set by the Secretary of the Treasury for National Research Service Awards prevailing on the date on which the period of appointment begins, multiplied, in any case in which the service that was required has been performed in part, by the percentage which the length of service that was not performed is to the length of the service that was required to be performed. The amount will be determined under the following formula:

$$A = 3(\theta + mi\theta)\frac{(t-s)}{(t)}$$

where

A = the amount the United States is entitled to recover;

θ = the cost of the clinical traineeship (including stipends and other trainee allowances);

m = the number of months since the trainee failed to perform obligated service;

i = the National Research Service Award rate on the date which the period of appointment begins divided by twelve;

t = the total number of months of the service obligation;

s = the number of months that have been served.

(2) Unless the Secretary extends the repayment period as provided in paragraph (e) of this section, the individual shall pay to the United States the total amount which the United States is entitled to recover under paragraph (g)(1) of this section immediately upon the date that the individual fails to begin or complete the period of obligated service (including failing to comply with the applicable terms and conditions of an extension or break in service granted the individual) or upon the date that the individual indicates his or her intention not to fulfill the service obligation as determined by the Secretary. The amount is considered a debt owed to the United States, with interest accruing monthly upon the total debt as provided under paragraph (g)(1) of this section.

[46 FR 39979, Aug. 5, 1981, as amended at 52 FR 18359, May 15, 1987]

PART 66—NATIONAL RESEARCH SERVICE AWARDS

Subpart A—Direct Awards

Sec.

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Sec.

Subpart B—Institutional Grants

66.201 Applicability.
66.202 Definitions.
66.203 Eligibility.
66.204 Application.
66.205 Requirements.
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66.208 Additional conditions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C 216); sec. 472, 88 Stat. 342 (42 U.S.C. 289*l*-1).

SOURCE: 48 FR 24880, June 3, 1983, unless otherwise noted.

Subpart A—Direct Awards

§ 66.101 Applicability.

The regulations in this subpart apply to National Research Service Awards made by the Secretary to individuals for research, and training to undertake research, under section 472(a)(1)(A) of the Public Health Service Act, as amended [42 U.S.C. 289*l*-1(a)(1)(A)].

§ 66.102 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "Nonprofit" institution means a corporation or association in which no part of the net earnings inures or may lawfully inure to the benefit of any private shareholder or individual.

(d) "Award" means a National Research Service Award under section 472 of the Act (42 U.S.C. 289*l*-1).

(e) "Residency" means post-graduate training for doctors of medicine, osteopathy, dentistry, optometry, and podiatry, nurses, and other individuals providing health care directly to patients, in which the majority of the time is spent in non-research clinical training.

(f) "Noncitizen national of the United States" means a person who, though not a citizen of the United States, owes permanent allegiance to the United States [8 U.S.C. 1101(a)(22)].

(g) "Predoctoral training" means training at the post-baccalaureate level in a program leading to the award of a doctor of philosophy or science, or equivalent degree. For purposes of Awards under the Minority Access to Research Careers programs of the National Institute of General Medical Sciences and the Alcohol, Drug Abuse, and Mental Health Administration, "predoctoral training" also means training in a program leading to the award of a baccalaureate degree in science or equivalent degree.

(h) "Postdoctoral training" means training of individuals holding a doctor of philosophy, science, medicine, dentistry, osteopathy, optometry, podiatry, veterinary medicine, engineering, nursing sciences, public health, or equivalent degree.

§ 66.103 Eligibility.

To be eligible for a National Research Service Award an individual must:

(a) Be a citizen, noncitizen national of the United States, or lawfully admitted to the United States for permanent residence at the time of application; and

(b) Propose to engage on a full-time basis in research, or training to undertake research, in a program specified in section 472(a)(1)(A) of the Act.

§ 66.104 Application.

(a) Eligible individuals may apply for an Award using the form and by the dates the Secretary prescribes.

(b) In addition to any other pertinent information that the Secretary may require, each application shall detail:

(1) The applicant's educational background and other qualifications and experience, including previous academic and professional degrees;

(2) The subject area of the proposed research or training;

(3) The proposed period of Award:

(4) If the proposed period of Award would provide the individual with aggregate support in excess of five years at the predoctoral level or three years

at the postdoctoral level, the justification for this request; and

(5) The availability of necessary resources facilities at the institution where the research or training would be conducted.

(Approved by the Office of Management and Budget under control number 0925-0002)

§ 66.105 Requirements.

The Secretary shall make an Award to an individual under this subpart only if:

(a) For any Award made for a period in excess of twelve months, other than an Award made for research training at the prebaccalaureate level, the individual has submitted to the Secretary a written assurance (in the manner the Secretary may prescribe) that he or she will satisfy the requirements of § 66.110;

(b) If the proposed research or training would take place at an institution other than one operated by the Public Health Service agencies listed in section 472(a)(1)(A) of the Act, the institution has submitted a written assurance (in the manner the Secretary may prescribe). The assurance shall indicate that:

(1) The applicant has been accepted to the institution for the purpose of engaging in the research or training for which an Award is being sought;

(2) The Award will not be used to support a residency; and

(3) In the event an Award is made the institution will make available to the applicant any resources and facilities described in the application as necessary to carry out the research or training; and

(c) The individual has submitted a written assurance (in the manner the Secretary may prescribe) that the Award to individuals will not be used to support a residency.

(Approved by the Office of Management and Budget under control number 0925-0002)

§ 66.106 Awards.

(a) Within the limits of funds available, the Secretary shall make Awards to those applicants:

(1) Who have satisfied the requirements of § 66.105; and

(2) Whose proposed research or training would, in the judgment of the Secretary, best promote the purposes of section 472(a)(1)(A) of the Act, taking into consideration among other pertinent factors:

(i) The scientific, technical, or educational merit of the particular proposal;

(ii) The availability of resources and facilities to carry it out;

(iii) The qualifications and experience of the applicant; and

(iv) The need for personnel in the subject area of the proposed research or training.

(b) In making Awards, the Secretary shall take account of the Nation's overall need for biomedical research by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(c) All Awards shall be in writing. Each shall specify:

(1) The period of the Award;

(2) The total recommended stipends and allowances provided for the entire Award period;

(3) The amount awarded for the initial year of that period (see § 66.107); and

(4) The amount of the payments to the institution for the cost of services provided the awardee by the institution during the initial year of that period (see § 66.108).

(d) Neither the approval of any application nor any Award shall commit or obligate the United States in any way to make additional, supplemental, continuation, or other Award with respect to any approved application or portion thereof.

(e) No individual may receive an aggregate of more than five years of support at the predoctoral level and three years at the postdoctoral level unless the Secretary waives, for good cause shown, this limitation for the individual. In determining what constitutes "good cause," the Secretary shall take into account such factors as whether the applicant proposes to pursue a combined program leading to the degrees of doctor of medicine and doctor of philosophy.

§ 66.107 Payments to awardees.

(a) Individuals receiving Awards shall be entitled to the stipends, tuition, fees, and allowances the Secretary may designate, taking into account the cost of living, and such other factors as the needs of the program and the availability of funds.

(b) The Secretary shall pay stipends, tuition, fees and allowances to the awardee or the sponsoring institution for payment to the awardee.

§ 66.108 Payments to institutions.

The institution shall be entitled to an allowance to help defray the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided to the individual by the institution. The Secretary shall determine the amount of payments based upon reasonable costs to the institution of establishing and maintaining the quality of research and training programs for which it receives support under this subpart. The Secretary may make payments to the institution either in advance or by way of reimbursement.

§ 66.109 Termination.

(a) The Secretary may terminate an Award prior to its normal expiration date:

(1) At the written request of the awardee; or

(2) If the Secretary finds that the awardee has materially failed to comply with the terms and conditions of the Award or to carry out the purpose for which it was made.

(b) In the event an Award is terminated, the Secretary shall notify the awardee in writing of this determination, the reasons for termination, the effective date, and any procedural rights available.

§ 66.110 Service, payback, and recovery requirements.

(a) Each individual who receives an Award for more than twelve months other than an Award for research training at the prebaccalaureate level shall upon completion of the Award engage for a period equal to the period of support (in excess of twelve months) in health research or teaching or, when in academic employment, any combination of research or teaching which is in accordance with the usual patterns of such employment.

(b) Except as provided in § 66.111, an individual subject to the requirements for service in paragraph (a) of this section must begin to undertake the service on a continuous basis within two years after the termination of his or her Award.

(c) If the individual fails to undertake or perform the service in accordance with the requirements of paragraph (a) of this section, the United States shall be entitled to recover from the individual an amount determined in accordance with the formula:

$$A = 0\frac{(t\text{-}s)}{(t)}$$

in which "A" is the amount the United States is entitled to recover; "0" is the sum of the total amount paid under one or more Awards to the individual less the amount paid for the initial twelve months; "t" is total number in months in the individual's sevice obligation; and "s" is the number of months of the obligation served by him or her in accordance with paragraph (a) of this section.

(d) Except as provided in § 66.111, the individual shall pay to the United States any amount which it is entitled to recover under paragraph (c) within a three-year period beginning on the date the United States becomes entitled to recover that amount. Interest shall accrue to the United States until any amount due it under paragraph (c) of this section is paid. The rate of interest will be fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States become entitled to recovery.

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983]

§ 66.111 Suspension, waiver, and cancellation.

(a) The Secretary may extend the period for undertaking service prescribed in § 66.110(d), permit breaks in service under § 66.110(b), or extend the period of repayment under § 66.110(d) if the Secretary determines that:

(1) An extension or break in service is necessary so the individual may complete his or her research training;

(2) Completion during the period would be impossible because the individual is temporarily disabled; or

(3) Completion during the period would involve a substantial hardship to the individual and failure to extend to the period would be against equity and good conscience.

(b) The Secretary may waive, in whole or in part, the obligation of the individual to repay pursuant to § 66.110(c) if the Secretary determines that:

(1) Fulfillment would be impossible because the individual is permanently and totally disabled; or

(2) Fulfillment would involve a substantial hardship to the individual and enforcement of the obligation would be against equity and good conscience.

(c) In making determinations under § 66.111 (a)(3) and (b)(2), the Secretary will take into consideration such factors as:

(1) The individual's present financial resources and obligations;

(2) The individual's estimated future financial resources and obligations;

(3) The reasons for the individual's failure to complete the requirements within the prescribed period, such as problems of a personal nature;

(4) The extent to which the individual has been engaged in activities encompassed by § 66.110(a);

(5) Whether the individual has received sufficient training to be qualified to perform any such activities;

(6) The unavailability of employment opportunities appropriate to the individual's education and training; and

(7) Any other extenuating circumstances.

(d) Any obligations of any individual under this subpart will be cancelled upon the death of that individual.

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983]

§ 66.112 Other HHS regulations that apply.

Several other regulations and policies may apply to individuals and institutions receiving payments under this subpart. These include, but are not limited to:

45 CFR Parts 6 and 8—Inventions and patents

45 CFR Part 46—Protection of human subjects

45 CFR Part 76—Debarment and suspension from eligibility for financial assistance

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

48 FR 24556—Guidelines for Research Involving Recombinant DNA Molecules published by the National Institutes of Health

[49 FR 38116, Sept. 27, 1984]

§ 66.113 Publications.

Publication, distribution, and disposition of all manuscripts and other materials resulting from an Award shall be subject to the conditions that all such materials shall bear appropriate acknowledgement of Department of Health and Human Services support and that the awardee shall furnish copies of these manuscripts or other materials as the Secretary may reasonably request.

§ 66.114 Copyright.

Where the work accomplished under an Award results in a book or other copyrightable material, the author is free to copyright the work, but the United States reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise

use, and to authorize others to use, all copyrightable or copyrighted material resulting from the Award.

§ 66.115 Additional conditions.

The Secretary may with respect to any Award or class of Awards impose additional conditions prior to or at the time of any Award when in the Secretary's judgment such conditions are necessary to assure the carrying out of the purposes of the Award, the interests of the public health, or the conservation of funds awarded.

Subpart B—Institutional Grants

§ 66.201 Applicability.

The regulations in this subpart apply to grants under section 472(a)(1)(B) of the Public Health Service Act, as amended [42 U.S.C. 289*l* - 1(a)(1)(B)], to public institutions and to nonprofit private institutions to enable these institutions to make National Research Service Awards to individuals for research, and training to undertake research, in programs specified in section 472(a)(1)(B) of the Act.

§ 66.202 Definitions.

The definitions in § 66.102 of Subpart A of this part apply to this subpart.

[48 FR 24880, June 3, 1983; 48 FR 33710, July 25, 1983]

§ 66.203 Eligibility.

To be eligible for a grant under this subpart, an applicant must be:

(a) A public or nonprofit private institution; and

(b) Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the Trust Territory of the Pacific Islands.

§ 66.204 Application.

(a) Application for a grant under this subpart shall be made on a form approved for that purpose by the Secretary. Applicants shall submit completed forms on or before the dates the Secretary may prescribe.

(b) In addition to any other pertinent information that the Secretary may require, each application shall set forth in detail:

(1) The subject area or areas in which the proposed research or training will be conducted;

(2) The resources and facilities available for use by recipients of Awards in carrying out this research or training;

(3) The names, qualifications, and experience of the program director and principal staff members who will be responsible for the proposed program;

(4) The criteria to be employed in selecting recipients of Awards;

(5) The estimated number of recipients of Awards under the grant;

(6) The proposed project period and a detailed budget and justification for the amount of grant funds requested; and

(7) Proposed methods for monitoring and evaluating the performance of individual recipients of Awards, as well as the overall program.

(Approved by the Office of Management and Budget under control number 0925-0022)

§ 66.205 Requirements.

(a) No Award shall be made to an individual from a grant under this subpart unless:

(1) For any Award made for a period in excess of twelve months, other than an Award made for research training at the baccalaureate level, the individual has submitted to the Secretary a written assurance (in the manner the Secretary may prescribe) that he or she will satisfy the requirements of § 66.110 of Subpart A of this part;

(2) The individual is a citizen or noncitizen national of the United States or has been lawfully admitted to the United States for permanent residence at the time of application;

(3) The Award includes a provision for termination in the event the recipient is found by the institution to have materially failed to comply with the terms and conditions of the Award or to carry out the purpose for which it was made; and

(4) The Award is not to be used to support a residency.

(b) No Award shall be made to an individual under such grant which

would provide that individual with aggregate support in excess of five years for predoctoral training and three years for postdoctoral training, unless the Secretary for good cause shown as provided in § 66.106(d) of Subpart A of this part, waives the application of the limitation with respect to that individual.

(c) The provisions of §§ 66.110 and 66.111 of Subpart A of this part constitute terms and conditions of any Award made from a grant under this subpart.

(Approved by the Office of Management and Budget under control number 0925-0022)

[48 FR 24880, June 3, 1983; 48 FR 33710, Ju[illegible]5, 1983]

§ 66.206 Grant awards.

(a) Within the limits of funds available, the Secretary shall award grants to those applicants:

(1) Whose applications have been reviewed and recommended for approval by the appropriate national advisory council or board;

(2) Who have satisfied the requirements of § 66.105; and

(3) Whose proposed programs would, in the judgment of the Secretary, best promote the purposes of section 472(a)(1)(B) of the Act, taking into consideration among other pertinent factors:

(i) The scientific, technical, or educational merit of the proposed program;

(ii) The adequacy of the resources and facilities available to the applicant;

(iii) The qualifications and experience of the program director and principal staff members;

(iv) The degree of the need for personnel in the subject area or areas of the proposed research or training;

(v) The extent to which the applicant, in making Awards, gives special consideration to physicians who agree to undertake a minimum of two years of biomedical research;

(vi) The administrative and management capability of the applicant;

(vii) The reasonableness of the proposed budget in relation to the proposed program; and

(viii) The adequacy of the methods for monitoring and evaluating the performance of individual recipients and the overall program.

(b) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3-5 years.

(c) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(d) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of any approved application.

§ 66.207 Other HHS regulations and policies that apply.

Several other regulations and policies apply to grants under this subpart. These include, but are not limited to:

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure
45 CFR Part 16—Procedures of the Departmental Grant Appeals Board
45 CFR Part 46—Protection of human subjects
45 CFR Part 74—Administration of grants
45 CFR Part 75—Informal grant appeals procedures
45 CFR Part 76—Debarment and suspension from eligibility for financial assistance
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearings under Part 80 of this Title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

48 FR 24556—Guidelines for Research Involving Recombinant DNA Molecules published by the National Institutes of Health

(Sec. 215, Public Health Service Act, 58 Stat. 690, as amended, (42 U.S.C. 216); sec. 472, Public Health Service Act, 88 Stat. 342 (42 U.S.C. 2891-1))

[49 FR 38116, Sept. 27, 1984]

§ 66.208 Additional conditions.

The Secretary may, with respect to any grant award, impose additional conditions prior to or at the time of any award when in the Secretary's judgment those conditions are necessary to assure or protect advancement of the approved program, the interests of the public health, or the conservation of grant funds.

PART 67—NATIONAL CENTER FOR HEALTH SERVICES RESEARCH GRANTS

Subpart A—Grants for Health Services, Research, Evaluation, and Demonstration Projects

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 35 (42 U.S.C. 216); sec. 305, 88 Stat. 363 (42 U.S.C. 242c), unless otherwise noted.

SOURCE: 43 FR 34472, Aug. 4, 1978, unless otherwise noted.

Subpart A—Grants for Health Services Research, Evaluation, and Demonstration Projects

§ 67.10 Purpose and scope.

The regulations of this subpart are applicable to the award through the National Center for Health Services Research of grants under section 305(b) of the Public Health Service Act (42 U.S.C. 242c(b)) to support identified health services research, evaluation, or demonstration projects to investigate:

(a) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;

(b) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and

(c) The design, construction, utilization, organization, and cost of facilities and equipment.

§ 67.11 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act.

(b) "Budget period" means the interval of time (usually 12 months) into which the project has been divided for budgetary and reporting purposes and for which the Government has made a financial commitment to fund a particular project.

(c) "Direct costs" means the costs that can be identified specifically with a particular cost objective, such as compensation of employees for the time and effort devoted specifically to the approved project, and the costs of materials acquired, consumed or expended specifically for the purpose of the approved project.

(d) "Grantee" means the public or nonprofit entity or individual that receives a grant under section 305(b) and this subpart for a health services research, evaluation or demonstration project and assumes legal and financial responsibility for the funds awarded and for the performance of the grant supported activity.

(e) "National Center for Health Services Research" means that unit of the Department of Health and Human Services established by section 305(a) of the Act.

(f) "Nonprofit" as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any shareholder or individual.

(g) "Project period" means the total period of time for which support for a project has been approved as specified in the grant award document. Such approval does not commit or obligate the Federal Government to any additional, supplemental or continuation support beyond the current budget period.

(h) "Principal investigator" means a single individual, designated in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project.

(i) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(j) "Peer review group" means a panel of experts who are neither officers nor employees, other than by reason of their appointment, of the United States qualified by training and experience in particular scientific and technical fields to give expert advice, in accordance with the provisions of this subpart, on the scientific and technical merit of grant applications.

§ 67.12 Eligibility.

(a) *Eligible applicants.* Any public or private nonprofit entity and any individual is eligible to apply for a grant under this subpart.

(b) *Eligible projects.* Grants pursuant to section 305(b) of the Act and this subpart may be made to eligible applicants for the purpose of assisting in meeting the costs of health services research, evaluation, or demonstration projects as described in § 67.10; *Provided,* That no grant may be made under this subpart for any health services research, evaluation, or demonstration project for which a grant under another provision of the Act (other than section 304) may be made.

§ 67.13 Application.

(a) An application for a grant under this subpart shall be submitted at such time and in such form and manner as the Secretary may prescribe, and shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the act, the regulations of this subpart and any additional terms or conditions of any grant awarded.

(b) In addition to such other information as the Secretary may require, an application under this subpart must contain the following:

(1) A description of the problem in the area of health services that the project will address;

(2) A description of the hypotheses that will be tested or the specific objectives that will be served by the project as they relate to the general problem area;

(3) A description of the manner in which the project will be organized and managed;

(4) A specification of the data that will be collected or used in the project;

(5) A description of the analytic procedures that will be employed in the project;

(6) The names and qualifications of the principal investigator and principal members of the staff that will be assigned to the project and their roles;

(7) A description of the facilities and resources that will be available to the applicant, if any; and

(8) A complete and detailed budget and justification for the amount of grant funds being requested.

§ 67.14 Evaluation of applications.

(a) *Projects with direct costs over the project period in excess of $35,000.* (1) All applications for grant support under this subpart for a project with estimated direct costs over the project period in excess of $35,000 will be submitted by the Secretary for review to a peer review group whose members will be selected based upon their training and experience in relevant scientific and technical fields taking into account among other factors:

(i) The level of formal education (e.g., M.A., Ph. D., M.D.) completed by the individual;

(ii) The extent to which the individual has engaged in relevant research, the capacities (e.g., principal investigators, assistant) in which the individual has done so, and the quality of such research;

(iii) The extent of the professional recognition received by the individual as reflected by awards and other honors received from scientific and professional organizations outside the Department of Health and Human Services; and

(iv) The need of the peer review group to include within its membership experts from various areas of specialization within relevant scientific and technical fields.

(2) In carrying out a review under this paragraph the peer review group will take into account where appropriate:

(i) The significance and originality from a scientific or technical standpoint of the goals of the project;

(ii) The adequacy of the methodology proposed to carry out the project;

(iii) The availability of data or the proposed plan to collect data required in the analyses;

(iv) The adequacy and appropriateness of the plan for organizing and carrying out the project;

(v) The qualifications of the principal investigator and proposed staff;

(vi) The reasonableness of the proposed budget in relation to the proposed project;

(vii) The adequacy of the facilities and resources available to the grantee; and

(viii) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

(3) The peer review group to which an application has been submitted pursuant to this paragraph shall make a written report to the Secretary on each application so submitted which shall contain the following parts:

(i) The first part shall consist of a factual summary of the proposed project, including a description of its purpose, scientific approach, location, total budget and manpower requirements.

(ii) The second part shall address the scientific and technical merit of the proposed project and shall consist of a critique of the proposed project with regard to the factors described in § 67.14(a)(2). This portion of the report shall include a set of recommendations to the Secretary with respect to the disposition of the application based upon its scientific and technical merit. The peer review panel may recommend that the Secretary approve, disapprove or defer a decision on the application in order to obtain further information. Where the peer review panel recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application. Where the peer review panel recommends approval, it shall also provide its recommendation regarding the appropriate project period and level of support for the proposed project.

(iii) The third part of the report shall describe the peer review panel's review of the importance of the prob-

lem that is to be addressed by the proposed project and its potential impact.

(b) *Project with direct costs over the project period of $35,000 or less.* (1) Applications for grant support under this subpart for a project with estimated direct costs over the project period of $35,000 or less (hereinafter sometimes referred to as "small grants") will be submitted by the Secretary for review to members of the staff of the National Center for Health Services Research and where desirable to assess the scientific merit of an application to at least two outside experts who are neither officers nor employees of the United States selected by the Director of the National Center for Health Services Research on the basis of their training and experience in particular scientific and technical fields, their knowledge of health services research and the application of research findings, and their special knowledge of the problem being addressed in the specific proposal.

(2) In carrying out a review under this paragraph, the reviewers will, take into account where appropriate:

(i) The significance and originality from a scientific or technical standpoint of the goals of the project;

(ii) The adequacy of the methodology proposed to carry out the project;

(iii) The availability of data or the proposed plan to collect data required in the analyses;

(iv) The adequacy and appropriateness of the plan for organizing and carrying out the project;

(v) The qualifications of the principal investigator and proposed staff;

(vi) The reasonableness of the proposed budget in relation to the project;

(vii) The adequacy of the facilities and resources available to the grantee; and

(viii) Where an application involves activities which could have an adverse effect upon humans, animals, or the environment, the adequacy of the proposed means for protecting against or minimizing such effects.

(3) Each reviewer to which an application has been submitted pursuant to this paragraph shall make a written report to the Secretary on each application so submitted. Each report shall summarize the reviewer's findings and provide recommendations with regard to approval, disapproval, or deferral of the application in order to obtain additional information.

§ 67.15 Disposition of applications.

On the basis of the Secretary's evaluation of the application as provided in § 67.16, the Secretary shall either (a) approve, (b) defer for a later decision, or (c) disapprove any application for grant assistance under this subpart: Disapproval of an application shall not preclude its reconsideration if the application is resubmitted in the same or a revised version at a later date.

§ 67.16 Grant award.

(a) *General.* (1) Within the limits of funds available for such purpose and subject to the limitation of section 308(c) of the Act, the Secretary may award grants to those applicants whose approved projects will in his judgment best promote the purposes of section 305(b) of the Act and the regulations of this subpart, taking into consideration:

(i) Recommendations made pursuant to § 67.14.

(ii) The appropriateness of the budget.

(iii) The extent to which the research proposal and the fiscal plan provide assurance that effective use will be made of grant funds.

(iv) The business management capability of the applicant.

(v) The competence and skill of the staff, especially the senior personnel, in light of the scope of the project.

(vi) The probable usefulness of the project results for dealing with national health care problems, policies, and programs.

(vii) The relative priority of the proposed project in light of the established priorities of the National Center for Health Services Research.

(2) In making any grant award the Secretary may add additional conditions to or require specific modifications in the project as proposed in the application including a different level of grant support from that requested

in the application. In such cases the Secretary will obtain either the written agreement of the applicant to proceed on such basis prior to making any grant award or such condition or modification will appear on the Notice of Grant Award.

(3) All grant awards shall be in writing. The Notice of Grant Award shall set forth the amount of funds awarded for the conduct of the approved project during the first budget period and the amount of annual support recommended for the remainder of the project period.

(4) The project for any grant under this subpart shall be specified in the Notice of Grant Award and shall begin no later than 9 months following the date of such award. In no case will a project be approved for a project period exceeding 5 years. Where the Secretary determines on the basis of a request by the grantee prior to the completion of the currently active grant that additional time is needed to permit the use of funds previously awarded but not expended, the approved project may be extended for a period of time not to exceed 12 months except that in no case may the project period exceed 5 years and 6 months. No additional support may be awarded for any portion of a project period in excess of 5 years.

(5) Neither the approval of any application nor the awarding of any grant shall commit or obligate the Federal Government in any way to make any additional, supplemental, continuation or other awards with respect to the project or any part of the project. For continuation support, grantees must make separate application annually and at such times and in such form as the Secretary may prescribe.

(b) *Determination of grant amount.* (1) The amount of any grant shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the project plus an additional amount for the indirect costs, if any, which will be calculated by the Secretary either:

(i) On the basis of the estimate of the actual indirect costs reasonable related to the project; or

(ii) On the basis of a percentage of all or a designated portion of the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs such as fringe benefit rates subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(2) For particular categories of small grants, such as dissertation research support, the Secretary may establish a limit on direct costs that is less than $35,000 for the project period. Such limit will be announced in advance of the deadline for receipt of applications for such grants.

(c) *Supplemental awards.* The Secretary may make supplemental awards during the course of any budget period of an approved project where the Secretary finds on the basis of the applicant's written request and such progress and accounting reports as the Secretary may require that the amount of the award initially approved was less than the amount necessary to carry out the approved project activities for that period, or that a supplemental award to fund incremental activities not initially approved for the period would substantially further the objectives of the project. The Secretary may also make a supplemental award where in his judgment such an award is necessary for the preparation of data in suitable form for transmittal in accordance with § 67.25. In cases where the award of any supplemental grant for a project exceeding $35,000 in direct costs would result in supplemental awards (excluding any supplemental award for preparation of data in suitable form for transmittal in accordance with § 67.25) during the project period in the aggregate exceeding twenty percent (20 percent) of the approved direct costs of the project, the Secretary will obtain the views of the peer review group which first evaluated the initial application prior to making any

such award. The peer review group shall submit a written report to the Secretary which describes the current status of the project, the basis for the request and the potential consequences of any request where the recommendation is to disapprove. In the case of small grants, the Secretary will not approve any supplemental grant award during the project period (excluding any supplemental award for preparation of data in suitable form for transmittal in accordance with § 67.25) which will in the aggregate exceed ten percent (10 percent) of the direct costs of the project.

(d) *Noncompeting continuation awards.* Where a grantee has filed an application for continuation support and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period of any previously approved project where the Secretary finds on the basis of such progress and accounting reports as may be required and after considering any recommendations made pursuant to this paragraph, that the project activities during the current budget period justify continued support of the project for an additional budget period. Each project with a project period in excess of 2 years and with direct costs over the project period in excess of $35,000 will be reviewed during the second budget period and during each subsequent budget period (except for the last budget period of the project period) by at least two members of the same peer group which reviewed the proposal in accordance with § 67.14. Such group shall review the application for continuation support and make recommendations to the Secretary concerning the disposition of such application based upon its evaluation of:

(1) The progress of the project in meeting project objectives,

(2) The appropriateness of the management of the project and allocation of resources within the project,

(3) The adequacy and appropriateness of the plan for the carrying out of the project during the budget period in light of the accomplishments during previous budget periods, and

(4) The reasonableness of the proposed budget for the subsequent budget period where the Secretary determines to continue support, the amount of grant award shall be determined in accordance with paragraph (b) of this section. Where the Secretary determines not to continue a project for an additional budget period, the grantee will be notified in writing before the end of the current budget period.

§ 67.17 Project requirements.

A project supported under this subpart must be conducted in accordance with the following requirements:

(a) The project shall be carried out in accordance with the approved application.

(b) The principal investigator shall be responsible for the conduct of the project unless replaced by another individual found by the Secretary to be qualified to carry out such responsibilities. Where the principal investigator becomes unable to function in such capacity, the Secretary shall be notified as soon as possible.

§ 67.18 Grant payments.

The Secretary will from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he determines such payments are necessary to promote prompt initiation and advancement of the approved project. The amounts otherwise payable to any grantee shall be reduced by:

(a) Amounts equal to the fair market value of any equipment or supplies furnished to such grantee at their request by the Secretary for the purpose of conducting the approved project; and

(b) Amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the government in connection with such approved project, if such officer or employee was assigned or detailed by the Secretary at the re-

quest of the grantee to perform such services.

§ 67.19 Use of project funds.

(a) Any funds granted pursuant to this subpart shall be expended by the grantee solely for carrying out the approved project in accordance with the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles, prescribed in Subpart Q of 45 CFR Part 74.

(b) The grantee may not in whole or in part delegate or transfer this responsibility for the use of such funds to any other person, or other legal entity, without the specific prior written approval of the Secretary.

(c) Prior approval by the Secretary is required whenever there is to be a significant change in the scope or nature of the approved project.

§ 67.20 Termination.

The termination of any grant under this subpart will be governed by the relevant provisions of Subpart M of 45 CFR Part 74 and the terms and conditions of the grant award. Where a grantee unilaterally terminates a portion of a grant, the Secretary may terminate such grant in whole where he determines that the remaining portion of the grant will not accomplish the purposes for which the grant was made.

§ 67.21 Nondiscrimination.

Recipients of grants under this subpart are advised that in addition to complying with the terms and conditions of these regulations, the following laws and regulations are applicable:

(a) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulation, 45 CFR Part 80 (prohibiting discrimination in Federally assisted programs on the ground of race, color, or national origin).

(b) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 974) and its implementing regulation, 45 CFR Part 84 (prohibiting discrimination in Federally assisted programs on the basis of handicap).

(c) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) and its implementing regulation, 45 CFR Part 86 (prohibiting discrimination on the basis of sex in Federally assisted education programs).

(d) Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

§ 67.22 Human subjects and animal welfare.

(a) No award may be made under this subpart unless the applicant has complied with 45 CFR Part 46 and other applicable requirements pertaining to the protection of human subjects.

(b) No award may be made under this subpart unless the applicant has complied with Chapter 1–43 of the Department of Health and Human Services Grants Administration Manual and any other requirements concerning animal welfare.

§ 67.23 Publications and copyright.

(a) *Copyright.* Except as may otherwise be provided under the terms and conditions of the award, th grantee is free to copyright any book or other copyrightable materials developed under the grant, subject to a royalty-free, nonexclusive and irrevocable license of the Department to reproduce, publish, alter, or otherwise use, and to authorize others to use the work for Government purposes. In any case in which a copyright has been obtained, the Secretary shall be so notified.

(b) *Publications.* Any reports, papers, statistics, or other materials developed from work supported in whole or in part by an award made under this subpart shall be submitted to the Secretary. The Secretary may make such materials available and disseminate the material on as broad a basis as practicable and in such form as to make such materials understandable.

§ 67.24 Confidentiality.

No information obtained by a grantee in the course of its health services research, evaluation, or demonstration activities may be used for any purpose other than the purpose for which it

was supplied (which shall include the disclosure of such information to the Secretary for carrying out his responsibilities under the Health Services Research, Health Statistics, and Medical Libraries Act of 1974, Pub. L. 93-353), unless authorized under regulations of the Secretary. Further, such information may not be published or released in other than statistical form if the person who supplied the information or who is described in it is identifiable unless such person has signed a written consent on such forms and in such manner as the Secretary may prescribe.

§ 67.25 Control of data.

Except as otherwise provided on the terms and conditions of the award and subject to the confidentiality requirements of § 67.24, all data collected or assembled for the purposes of carrying out health services research, demonstration, or evaluation projects supported under this subpart shall be made available to the Secretary upon request.

§ 67.26 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this subpart: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total or a selected element of the reimbursable direct costs incurred.

(b) *Accounting for royalties.* Royalties received by grantees from copyrights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under grant shall be accounted for as follows:

(1) Royalties received during the period of grant support as a result of copyrights or patents shall be retained by the grantee and in accordance with the terms and conditions of the grant, be disposed of under either, or a combination of the following options:

(i) Used by the grantee for any purposes that further the objectives of the legislation under which the grant was made.

(ii) Deducted from the total project costs for the purpose of determining the net costs on which the Federal share of costs will be based.

(2) Royalties received after the completion or termination of grant support shall be disposed of as follows:

(i) Patent royalties shall be governed by agreements between the Assistant Secretary for Health, Department of Health and Human Services, and the grantee pursuant to the Department's patent regulations (45 CFR Parts 6 and 8).

(ii) Copyright royalties may be retained by the grantee, unless the terms and conditions of the grant or a specific agreement negotiated between the Secretary and the grantee provide otherwise, except State or local government grantees which receive royalties in excess of $200 a year shall return the Federal share of the excess amount (computed by applying the percentage of Federal participation in the cost of the grant supported project to the excess amount) to the Federal Government, unless specific agreement provides otherwise.

(c) *Grant closeout*—(1) *Date of final accounting.* In addition to such other special and periodic accounting as the Secretary may require, a grantee shall render with respect to each approved project a full account, as provided herein, as of the termination of grant support which shall be at the end of the project period or the date of any termination of grant support pursuant to the applicable provisions of Subpart M of 45 CFR Part 74 and the terms and conditions of the grant award.

(2) *Final settlement.* There shall be payable to the United States as final settlement with respect to each approved project the total sum of (i) any

amount not accounted for pursuant to paragraph (a) of this section and (ii) any other amounts due pursuant to the applicable provisions of 45 CFR Part 74 and the terms and conditions of the grant award. Such total sum shall constitute a debt owed by the grantee to the United States and shall be recovered from the granteee or its successors or assignees by set-off or other action as provided by law.

§ 67.27 Applicability of 45 CFR Part 74.

The provision of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to States and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to other grantee organizations under this subpart:

45 CFR PART 74

Subpart:
- A—General.
- B—Cash Depositories.
- C—Bonding and Insurance.
- D—Retention and Custodial Requirements for Records.
- F—Grant-Related Income.
- G—Matching and Cost Sharing.
- K—Grant Payment Requirements.
- L—Budget Revision Procedures.
- M—Grant Closeout, Suspension, and Termination.
- O—Property.
- Q—Cost Principles.

§ 67.28 Additional conditions.

The Secretary may, with respect to any grant awarded under this subpart, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project or the conservation of grant funds.

Subpart B—Grants for Health Services Research Centers

AUTHORITY: Sec. 215, 58 Stat. 690 (42 U.S.C. 216); sec. 305(d), as amended, 88 Stat. 364; (42 U.S.C. 242c(d)).

SOURCE: 41 FR 5226, Feb. 4, 1976, unless otherwise noted.

§ 67.101 Purpose and scope.

(a) The regulations of this subpart are applicable to the award of grants under section 305(d) of the Public Health Service Act, as amended, to assist in meeting the costs of planning, establishing and operating multidisciplinary Health Services Research Centers by providing support for both permanent staff composed of experts from different disciplines and the administrative costs of carrying out multidisciplinary health services research, evaluations and demonstrations respecting:

(1) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;

(2) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and

(3) The design, construction, utilization, and cost of facilities and equipment.

(b) Additional support awarded under this subpart, for National Special Emphasis Centers is intended to support staff, research, demonstration, and evaluation projects, training programs, and administrative costs for activities appropriate to the particular area of special emphasis.

§ 67.102 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(c) "Nonprofit" as applied to a private entity, means that no part of the net earnings of such entity inures or may lawfully inure to the benefit of any shareholder or individual.

(d) "Project period" means the total period of time for which support for a project has been approved as specified in the grant award document. Such approval does not commit or obligate the Federal government to any additional, supplemental or continuation

support beyond the current budget period.

(e) "Budget period" means the interval of time (usually 12 months) into which the project has been divided for budgetary and reporting purposes and for which the Government has made a financial commitment to fund a particular project.

(f) "Center" means a Health Services Research Center supported under this subpart.

(g) "National Special Emphasis Center" mean a Center which directs a substantial portion of its efforts in research training, technical assistance, and other appropriate activities to a particular aspect of health care delivery specified by the Secretary and requiring a particular kind of scientific expertise. Such Centers shall include:

(1) A Health Care Technology Center, which shall focus on all forms of technology, including computers and electronic devices, and its applications in health care delivery;

(2) A Health Care Management Center, which shall focus on the improvement of administration and organization in the health field, the training and retraining of administrators of health care enterprises, and the development of leaders, planners and policy analysts in the health field; and

(3) Such other Centers as the Secretary shall deem appropriate, provided that formal notification of the competition for a grant award and designation as a National Special Emphasis Center under this subpart shall be made at least ninety (90) days prior to the closing date for filing applications for Center grants.

(h) "State" means one of the 50 States, the District of Columbia, Puerto Rico, Guam, Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(i) "Grantee" means the public or nonprofit private entity that receives a grant under section 305(d) of the Act and this subpart and assumes legal and financial responsibility for the funds awarded and for the performance of the grant supported activity.

(j) "Director" means a single individual, designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific, technical, and administrative direction of the Center.

§ 67.103 Eligibility.

Any public or nonprofit private entity located in a State is eligible to apply for a grant under this subpart; *Provided,* That no entity is eligible for assistance for more than one Center at any one time.

§ 67.104 Application.

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such manner as the Secretary may prescribe.[1]

(b) The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the Act, the regulations of this subpart and the terms and conditions of any grant award.

(c) In addition to such other pertinent information as the Secretary may require, an application for a grant under this subpart shall contain the following:

(1) A description of the manner in which the applicant intends to plan and establish a Center, including a timetable for making the proposed Center operational;

(2) A description of the staff of the proposed Center, including their qualifications, academic training, responsibilities and functions;

(3) A description of the manner in which the staff will be organized and supervised to carry out the proposed activities of the Center;

(4) A description of the applicant's plan for providing at the Center educational opportunities to students, health professionals and other appropriate individuals;

(5) A description of the applicant's plan for sharing the knowledge and expertise of the Center's staff by providing technical assistance to appro-

[1] Applications and instructions are available from the Director, Review and Advisory Services, National Center for Health Services Research, Health Resources Administration, 5600 Fishers Lane, Rockville, Maryland 20852, Room 15-35.

priate organizations and individuals and through other forms of public and community services;

(6) A description of the applicant's plan for disseminating the Center's research findings to appropriate forums;

(7) A description of the need of the region in which the proposed Center will be located for a Center and a description of the areas of research which the applicant expects the Center to address by virtue of particular problems and characteristics of the local health care delivery system;

(8) A description of the organizational structure of the applicant and the nature of any relationship with and access to health care delivery systems in which research activities can be undertaken and research findings tested;

(9) A description of the procedures by which research projects will be selected, including the methodology to be utilized in ensuring that such projects will be selected on the basis of (i) the regional or national importance of the problem to be addressed, (ii) the unique potential for definitive research on a problem, and (iii) opportunities for local application of the research findings;

(10) A budget which allocates the total support both by type of expenditure and by the activities identified in paragraphs (c) (1), (4), (5), (6), and (9) of this section;

(11) A description of the resources which the applicant plans to make available to the proposed Center;

(12) A description of the proposed Center's relationships with other academic institutions and research organizations with regard to the impact of such relationships on the quality and scope of the Center's research and the responsiveness of its project selection to local, regional and national priorities; and

(13) Assurances satisfactory to the Secretary that the Center will meet the operational requirements of § 67.107 when it becomes operational.

(d) In addition to the material specified in paragraph (c) of this section, an application for a grant with a designation as a National Special Emphasis Center shall also contain the following:

(1) A description of the areas of research which the applicant expects the Center to address by virtue of the particular problems and characteristics of the field of special emphasis;

(2) A description of the nature of any relationships with and access to health care delivery systems that would enhance the ability to carry out research, evaluations, and demonstrations in management, technology, or other areas of special emphasis;

(3) A description of the procedures by which special emphasis projects will be selected including the methodology to be utilized in ensuring that such projects will be selected on the basis of national importance of the problem being addressed and the unique potential for definitive research on a problem;

(4) A description of the resources which the applicant plans to make available to enhance the special emphasis activities;

(5) A description including a budget, of the proposed Center's plan for disseminating its research findings to groups and individuals particularly concerned with the area of special emphasis; and

(6) Assurances satisfactory to the Secretary that it will meet the additional operational requirements of § 67.107 when it becomes operational.

§ 67.105 Evaluation and disposition of applications.

(a) *Evaluation.* (1) All applications for a grant under this subpart will be submitted by the Secretary for review to a panel of experts who are neither officers or employees of the United States and who possess qualifications necessary to evaluate both the applicant's proposed method of planning, establishing and operating a Center and the potential of the proposed Center to make a valuable scientific contribution (hereinafter referred to as the review panel).

(2) The review panel to which an application has been submitted pursuant to paragraph (a)(1) of this section shall make a written report to the Secretary on each application so submitted. Each report shall consist of the following parts:

(i) The first part shall consist of a factual summary of the proposed Center, including a synopsis of the information required under § 67.104(c). If the applicant is applying for an award as a National Special Emphasis Center a factual summary of the information provided in accordance with § 67.104(d) shall also be submitted.

(ii) The second part shall address the scientific and technical merit of the application and shall consist of a critique of the proposal and an assessment of the adequacy of the applicant's plan and available resources for meeting the requirements of § 67.107.

(iii) The third part, where appropriate, shall address the scientific and technical merit of the application for an additional award for a National Special Emphasis Center. This part of the report shall consist of a critique of the proposal and an assessment of the adequacy of the applicant's plan and available resources for meeting the additional requirements of § 67.107.

(iv) The fourth part shall describe the panel's assessment of the relevance of the proposed program to regional or national health care issues.

(v) The fifth part shall consist of a set of recommendations to the Secretary with respect to the disposition of the application:

(A) The panel may recommend that the Secretary approve, disapprove, or defer a decision in order to gather further information on an application for support as a Health Services Research Center. If the panel recommends approval, it shall also provide its recommendation regarding an appropriate project period and an appropriate level of support. If it recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application.

(B) The panel may also recommend that the Secretary approve, disapprove, or defer a decision in order to gather further information on an application for additional support as a National Special Emphasis Center. If the panel recommends approval, it shall also provide its recommendation regarding an appropriate project period and an appropriate level of support. If it recommends deferral, it shall specify the additional information it deems necessary for an adequate review of the application.

(b) *Disposition.* On the basis of the Secretary's evaluation of the application and taking into consideration any recommendations made pursuant to paragraph (a) of this section, the Secretary shall either (1) approve, (2) defer for a later decision or (3) disapprove any application for grant assistance under this subpart. Such disapproval of an application shall not preclude its reconsideration if the application is resubmitted in the same or a revised version at a later date.

§ 67.106 Grant awards.

(a) *General.* (1) Within the limits of funds available for such purpose, the Secretary may award a grant to those applicants whose approved proposed Centers will in his judgment best promote the purposes of section 305(d) of the Act and this subpart, taking into consideration:

(i) Recommendations made pursuant to § 67.105.

(ii) The appropriateness of the proposed budget and the extent to which the fiscal plan provides assurance that effective use would be made of grant funds.

(iii) The capability of the applicant as demonstrated by organizational and institutional arrangements to successfully operate the proposed Center.

(iv) The qualifications, achievements, and commitment of the senior personnel.

(v) The strength and scientific integrity of the general program and approach of the proposed Center.

(vi) The nature of the sponsoring institution's commitment to the proposed Center and the relative importance it ascribes to the endeavor.

(vii) The past success and future potential of the proposed Center's personnel in receiving permanent and project related support from other sources.

(viii) The extent to which a proposed Center's planning process incorporates the concerns of pertinent constituents and reflects an awareness of significant research problems in health services.

(ix) The strength of the relationship the proposed Center has developed with components of a local health care system in which specific projects will be conducted and research findings tested.

(x) The integration of disciplinary interests within the proposed Center and the coordination of the research program with training and educational efforts.

However, no grant may be awarded which will result in more than twenty per centum (20%) of all Centers supported under this subpart being located in any one HHS region, except that this restriction shall not operate to proscribe awarding at least two grants under this subpart to institutions located in any single HHS region; *Provided,* That to the extent feasible, the Secretary will make such grants as will result in at least six Centers being operational in each fiscal year.

(2) In making any grant award the Secretary may add additional conditions to or require specific modifications in the Center as proposed in the application including a different level of grant support from that requested in the application. In such cases the Secretary will obtain either the written agreement of the applicant to proceed on such basis prior to making any grant award or such condition or modification will appear on the grant award notice.

(3) All grant awards shall be in writing. The Notice of Grant Awarded shall set forth the amount of funds awarded for the conduct of the Center during the first budget period and the amount of support recommended for the remainder of the project period.

(4) The project period for any grant under this subpart shall be specified in the Notice of Grant Awarded and shall begin no later than nine months following the date of such award. In no case may a project period exceed five years; *Provided,* That the approved project period may be extended for a period not to exceed six months beyond five years where the Secretary determines on the basis of a request by the grantee prior to the termination of the currently active grant that such additional time is needed to permit the use of funds previously awarded but not expended. No additional support may be awarded for this period.

(5) Neither the approval of any application nor the awarding of any grant shall commit or obligate the Federal Government in any way to make any additional, supplemental, continuation or other awards with respect to the Center or any part of the Center. For continuation support, grantees must make separate application annually and at such times and in such form as the Secretary may prescribe.

(b) *Determination of grant amount.* The amount of any grant shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of the direct costs of the Center plus an additional amount for the indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all or a designated portion of the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs.

Such award may include an estimated provisional amount for indirect costs or for designated direct costs such as fringe benefit rates subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(c) *Supplemental awards.* The Secretary may make supplemental awards during the course of any budget period of an approved Center where the Secretary finds on the basis of the applicant's written request and such progress and accounting reports as the Secretary may require that the amount of the award initially approved was less than the amount necessary to carry out the approved Center activities for that period. The Secretary may also make a supplemental award where in his judgment such

an award is necessary for the preparation of data in suitable form for transmittal in accordance with § 67.113. However, where the making of any supplemental award would result, in any budget period, in supplemental awards exceeding twenty per centum (20%) of the original award for direct Center costs in that budget period, the Secretary will prior to making such award obtain the recommendation of the review panel which evaluated the Center's initial application. The review panel shall submit a written report to the Secretary which describes the current status of the Center, the basis for the request, the panels recommendation concerning the request and the potential consequences of any request that is disapproved.

(d) *Non-competing continuation awards.* Where a grantee has filed an application for continuation support and within the limits of funds available for this purpose, the Secretary may make a grant award for an additional budget period for any previously approved Center where the Secretary finds on the basis of such progress and accounting reports as may be required that the Center's activities during the current budget period justify continued support of the project for an additional budget period. Where the Secretary determines to continue support, the amount of grant award shall be determined in accordance with paragraph (b) of this section. Where the Secretary determines not to continue a project for an additional budget period, the grantee will be notified in writing before the end of the current budget period. In addition, where he determines such support is necessary, the Secretary may provide financial support for the orderly phase-out of the supported activity.

§ 67.107 Operational requirements.

(a) Any Center supported under this subpart shall:

(1) Have a full-time Director who possesses a demonstrated capacity for sustained productivity and leadership in health services research, demonstrations, and evaluations. The Director shall oversee the research program and the general operation of the Center and shall to the extent practicable directly participate in research activities. Where the Director of a Center becomes unable to function in such capacity, the grantee shall so inform the Secretary as quickly as possible. Within five (5) days, the grantee shall designate an Interim Director and inform the Secretary of the name of such individual. Within ninety (90) days, the grantee shall nominate an Acting Director who, if approved by the Secretary, shall serve in that capacity until the end of the budget period. The failure to obtain Secretarial approval of a new Director in the prescribed period of time shall result in immediate suspension of the grant;

(2) Have such additional full-time professional staff representing various disciplines relevant to health services research as necessary to plan, establish and operate the proposed Center and to carry out or administer research projects undertaken with the Center. The number and expertise of the staff shall be determined by the size of the proposed Center, the availability to it of staff resources other than its own immediate staff, and the nature and scope of the problems which its research will address;

(3) Be located within an established academic or research institution with available resources appropriate to the proposed activities to be conducted by the Center;

(4) Have written agreements with clinical settings which provide for settings appropriate for the initiation and evaluation of experiments in health services research;

(5) Select problems in health services for research, demonstrations and evaluations respecting:

(i) The accessibility, acceptability, planning, organization, distribution, technology, utilization, quality, and financing of health services and systems;

(ii) The supply and distribution, education and training, quality, utilization, organization, and cost of health manpower; and

(iii) The design, construction, utilization, organization, and cost of facilities and equipment on the basis of (A) their regional or national importance, (B) the unique potential for definitive

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research on the problem, (C) the opportunities for local application of the research findings;

(6) Provide educational opportunities, through formal mechanisms, for university students, health professionals or other appropriate individuals;

(7) Provide for the dissemination of its research findings, subject to the requirements for confidentiality as set forth in section 308(d) of the Act and § 67.112;

(8) Provide, through a formal mechanism, for consultations and technical assistance to concerned individuals and groups of the geographical area in which the Center will be located.

(b) National Special Emphasis Centers shall, in addition to the requirements of paragraph (a) of this section:

(1) Provide for the dissemination of its research findings on a national scale to groups and individuals particularly concerned with the area of special inquiry;

(2) Select problems in its area of special emphasis for research, demonstration and evaluation on the basis of the national importance of the problem being addressed and the unique potential for definitive research;

(3) Provide, through a formal mechanism, for consultations and technical assistance appropriate to its area of special expertise to concerned individuals and groups on a national scale; and

(4) Employ all of the resources made available to the Center by virtue of its National Special Emphasis designation in planning, conducting and monitoring research, training, technical assistance, and other appropriate activities solely in its area of special emphasis.

§ 67.108 Grant payments.

The Secretary shall from time to time make payments to the grantee of all or a portion of any grant award, either by way of reimbursement for expenses incurred in the budget period, or in advance for expenses to be incurred, to the extent he determines such payments are necessary to promote prompt initiation and advancement of the approved Center. The amounts otherwise payable to any grantee shall be reduced by:

(a) Amounts equal to the fair market value of any equipment or supplies furnished to such grantee at their request by the Secretary for the purpose of planning, establishing or operating the Center; and

(b) Amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the government in connection with such Center, if such officer or employee was assigned or detailed by the Secretary at the request of the grantee to perform such services.

§ 67.109 Use of project funds.

(a) Any funds granted pursuant to this subpart shall be expended by the grantee solely for planning, establishing or operating the approved Center in accordance with the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(b) The grantee may not in whole or in part delegate or transfer this responsibility for the use of such funds to any other person, or other legal entity, without the specific prior written approval of the Secretary.

(c) Prior approval by the Secretary is required whenever there is to be a significant change in the scope or nature of the Center's approved activities.

§ 67.110 Nondiscrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall on account of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing Title VI which applies to grants made under this subpart have been issued by the Secretary with the approval of the President (45 CFR Part 80).

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped person in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

(c) Grant funds used for remodeling, alteration or repairs shall be subject to the conditions that the grantee shall comply with the requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, and with the applicable rules, regulations, and procedures prescribed pursuant thereto.

§ 67.111 Publications and copyright.

(a) *Copyright.* Except as may otherwise be provided under the terms and conditions of the award, the grantee is free to copyright any book or other copyrightable materials developed under the grant, subject to a royalty-free, nonexclusive and irrevocable license of the Department to reproduce, publish, alter or otherwise use, and to authorize others to use the work for Government purposes. In any case in which a copyright has been obtained, the Secretary shall be so notified.

(b) *Publications.* Any reports, papers, statistics, or other materials developed from work supported in whole or in part by an award made under this subpart shall be submitted to the Secretary. The Secretary may make such materials available and disseminate the material on as broad a basis as practicable and in such form as to make such materials understandable.

§ 67.112 Confidentiality.

No information obtained by a Center in the course of its health services research activities directly supported under this subpart may be used for any purpose other than the purpose for which it was supplied (which shall include the disclosure of such information to the Secretary for carrying out his responsibilities under the Health Services Research, Health Statistics, and Medical Libraries Act of 1974 (Pub. L. 93-353), unless authorized under regulations of the Secretary. Further, such information may not be published or released in other than statistical form if the person who supplied the information or who is described in it is identifiable unless such person has signed a written consent on such forms and in such manner as the Secretary may prescribe. For purposes of this section and § 67.113, the term "directly supported", as it relates to health services research, demonstration, or evaluation projects, means discrete, identifiable projects supported under this subpart and not to solely the provision of administrative and staff support for the Center.

§ 67.113 Control of data.

Except as otherwise provided in the terms and conditions of the award and subject to the confidentiality requirements of § 67.112, all data collected or assembled for the purposes of carrying out health services research, demonstration, or evaluation projects directly supported under this subpart (as that term is defined in § 67.112) shall be made available to the Secretary upon request.

§ 67.114 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this subpart; *Provided however,* That when the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for royalties.* Royalties received by grantees from copy-

rights on publications or other works developed under the grant, or from patents or inventions conceived or first actually reduced to practice in the course of or under such grant, shall be accounted for as follows:

(1) *State and local governments.* When the grantee is a State or local government as defined in 45 CFR 74.3, royalties shall be accounted for as provided in 45 CFR 74.44.

(2) *Grantees other than State and local governments.* Where the grantee is not a State or local government as so defined, royalties shall be accounted for as follows:

(i) Patent royalties, whether received during or after the project period, shall be governed by agreements between the Assistant Secretary for Health, Department of Health and Human Services, and the grantee, pursuant to the Department's patent regulations (45 CFR Parts 6 and 8).

(ii) Copyright royalties, whether received during or after the grant period, shall first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials; and any royalties in excess of the costs of publishing or producing such materials shall be distributed in accordance with Chapter 1-420 or the Department of Health and Human Services Grants Administration Manual.[2]

(c) *Grant closeout*—(1) *Date of final accounting.* In addition to such other special and periodic accounting as the Secretary may require, a grantee shall render with respect to each Center a full account, as provided herein, as of the termination of grant support which shall be (i) the end of the project period, or (ii) the date of any termination of grant support pursuant to Subpart M of 45 CFR Part 74.

(2) *Final settlement.* There shall be payable to the United States as final settlement with respect to each approved project the total sum of (i) any amount not accounted for pursuant to paragraph (a) of this section and (ii) any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74. Such total sum shall constitute a debt owed by the grantee to the United States and shall be recovered from the grantee or its successors or assignees by set-off or other action as provided by law.

§ 67.115 Reports.

Each grant awarded under this subpart shall be subject to the condition that the grantee shall file written notification with the Secretary of each research, demonstration or evaluation project undertaken by the Center on the date that such project is initiated. Such notification shall include:

(a) A description of the project, including the hypotheses to be tested or the objectives to be pursued;

(b) The names of the principal investigators and the principal staff members that will be assigned to the project; and

(c) A budget, including an identification of the source of funds.

§ 67.116 Human subjects.

No award may be made under this Subpart unless the applicant has complied with 45 CFR Part 46 and other applicable requirements pertaining to the protection of human subjects.

§ 67.117 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to States and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to other grantee organizations under this subpart:

45 CFR PART 74

Subpart:
- A General.
- B Cash Depositories.
- C Bonding and Insurance.
- D Retention and Custodial Requirements for Records.
- F Grant-Related Income.
- G Matching and Cost Sharing.

[2] The Department of Health and Human Services Grants Administration Manual is available for public inspection and copying at the Department's and Regional Offices' information centers listed in 45 CFR 5.31 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Subpart:
K Grant Payment Requirements.
L Budget Revision Procedures.
M Grant Closeout, Suspension, and Termination.
O Property.
Q Cost Principles.

§ 67.118 Additional conditions.

The Secretary may, with respect to any grant awarded under this subpart, impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved Center or the conservation of grant funds.

SUBCHAPTER F—QUARANTINE, INSPECTION, LICENSING

PART 71—FOREIGN QUARANTINE

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71.55 Dead bodies.

AUTHORITY: Sec. 215 of Public Health Service (PHS) Act, as amended (42 U.S.C. 216); secs. 361-369, PHS Act, as amended (42 U.S.C. 264-272); E.O. 12452 of December 22, 1983, 48 FR 56927.

SOURCE: 50 FR 1519, Jan. 11, 1985, unless otherwise noted.

Subpart A—Definitions and General Provisions

§ 71.1 Scope and definitions.

(a) The provisions of this part contain the regulations to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the States or possessions of the United States. Regulations pertaining to preventing the interstate spread of communicable diseases are contained in 21 CFR Parts 1240 and 1250.

(b) As used in this part the term:

"Carrier" means a ship, aircraft, train, road vehicle, or other means of transport, including military.

"Communicable disease" means an illness due to a specific infectious agent or its toxic products which arises through transmission of that agent or its products from an infected person or animal or a reservoir to a susceptible host, either directly, or indirectly through an intermediate animal host, vector, or the inanimate environment.

"Contamination" means the presence of undesirable substances or material which may contain infectious agents or their toxic products.

"Controlled Free Pratique" means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

"Deratting Certificate" means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, recording the inspection and deratting of the ship.

"Deratting Exemption Certificate" means a certificate issued under the instructions of the Director, in the form prescribed by the International Health Regulations, recording the inspection and exemption from deratting of the ship which is rodent free.

"Detention" means the temporary holding of a person, ship, aircraft, or other carrier, animal, or thing in such place and for such period of time as may be determined by the Director.

"Director" means the Director, Centers for Disease Control, Public Health Service, Department of Health and Human Services, or his/her authorized representative.

"Disinfection" means the killing of infectious agents or inactivation of their toxic products outside the body by direct exposure to chemical or physical agents.

"Disinfestation" means any chemical or physical process serving to destroy or remove undesired small animal forms, particularly arthropods or rodents, present upon the person, the clothing, or the environment of an individual, or upon animals and carriers.

"Disinsection" means the operation in which measures are taken to kill the insect vectors of human disease present in carriers and containers.

"Educational purpose" means use in the teaching of a defined educational program at the university level or equivalent.

"Exhibition purpose" means use as a part of a display in a facility comparable to a zoological park or in a trained animal act. The animal display must be open to the general public at routinely scheduled hours on 5 or more days of each week. The trained animal act must be routinely scheduled for multiple performances each week and open to the general public except for reasonable vacation and retraining periods.

"Ill person" means a person who:

(1) Has a temperature of 100 °F. (or 38 °C.) or greater, accompanied by a rash, glandular swelling, or jaundice, or which has persisted for more than 48 hours; or

(2) Has diarrhea, defined as the occurrence in a 24-hour period of three or more loose stools or of a greater than normal (for the person) amount of loose stools.

"International Health Regulations" means the International Health Regulations of the World Health Organization, adopted by the Twenty-Second World Health Assembly in 1969, as amended by the Twenty-Sixth World Health Assembly in 1973, the Thirty-Fourth World Health Assembly in 1981, and as may be further amended.

"International voyage" means: (1) In the case of a carrier, a voyage between ports or airports of more than one country, or a voyage between ports or airports of the same country if the ship or aircraft stopped in any other country on its voyage; or (2) in the case of a person, a voyage involving entry into a country other than the country in which that person begins his/her voyage.

"Isolation" means: (1) When applied to a person or group of persons, the separation of that person or group of persons from other persons, except the health staff on duty, in such a manner as to prevent the spread of infection; or (2) when applied to animals, the separation of an animal or group of animals from persons, other animals, or vectors of disease in such a manner as to prevent the spread of infection.

"Military services" means the U.S. Army, the U.S. Air Force, the U.S. Navy, and the U.S. Coast Guard.

"Scientific purpose" means use for scientific research following a defined protocol and other standards for research projects as normally conducted at the university level. The term also includes the use for safety testing, potency testing, and other activities related to the production of medical products.

"Surveillance" means the temporary supervision of a person who may have or has been exposed to a communicable disease.

"U.S. port" means any seaport, airport, or border crossing point under the control of the United States.

"United States" means the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

"Vector" means an animal (including insects) or thing which conveys or is capable of conveying infectious agents from a person or animal to another person or animal.

§ 71.2 Penalties.

Any person violating any provision of these regulations shall be subject to a fine of not more than $1,000 or to imprisonment for not more than 1

year, or both, as provided in section 368 of the Public Health Service Act (42 U.S.C. 271).

§ 71.3 Designation of yellow fever vaccination centers; Validation stamps.

(a) *Designation of yellow fever vaccination centers.* (1) The Director is responsible for the designation of yellow fever vaccination centers authorized to issue certificates of vaccination. This responsibility is delegated by the Director to a State or territorial health department with respect to yellow fever vaccination activities of non-Federal medical, public health facilities, and licensed physicians functioning within the respective jurisdictions of a State or territorial health department. Designation may be made upon application and presentation of evidence satisfactory to a State or territorial health department that the applicant has adequate facilities and professionally trained personnel for the handling, storage, and administration of a safe, potent, and pure yellow fever vaccine. Medical facilities of Federal agencies are authorized to obtain yellow fever vaccine without being designated as a yellow fever vaccination center by the Director.

(2) A designated yellow fever vaccination center shall comply with the instruction issued by the Director or by a delegated officer or employee of a State or territorial health department for the handling, storage, and administration of yellow fever vaccine. If a designated center fails to comply with such instruction, after notice to the center, the Director or, for non-Federal centers, a State or territorial health department, may revoke designation.

(b) *Validation stamps.* International Certificates of Vaccination against cholera and yellow fever issued for vaccinations performed in the United States shall be validated by:

(1) The Seal of the Public Health Service; or

(2) The Seal of the Department of State; or

(3) The stamp of the Department of Defense; or

(4) The stamp issued to the National Aeronautics and Space Administration; or

(5) The stamp issued by a State or territorial health department; or

(6) An official stamp of a design and size approved by the Director for such purpose.

Subpart B—Measures at Foreign Ports

§ 71.11 Bills of health.

A carrier at any foreign port clearing or departing for any U.S. port shall not be required to obtain or deliver a bill of health.

Subpart C—Notice of Communicable Disease Prior to Arrival

§ 71.21 Radio report of death or illness.

(a) The master of a ship destined for a U.S. port shall report immediately to the quarantine station at or nearest the port at which the ship will arrive, the occurrence, on board, of any death or any ill person among passengers or crew (including those who have disembarked or have been removed) during the 15-day period preceding the date of expected arrival or during the period since departure from a U.S. port (whichever period of time is shorter).

(b) The commander of an aircraft destined for a U.S. airport shall report immediately to the quarantine station at or nearest the airport at which the aircraft will arrive, the occurrence, on board, of any death or ill person among passengers or crew.

(c) In addition to paragraph (a) of this section, the master of a ship carrying 13 or more passengers must report by radio 24 hours before arrival the number of cases (including zero) of diarrhea in passengers and crew recorded in the ship's medical log during the current cruise. All cases of diarrhea that occur after the 24 hour report must also be reported not less than 4 hours before arrival.

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Subpart D—Health Measures at U.S. Ports: Communicable Diseases

§ 71.31 General provisions.

(a) Upon arrival at a U.S. port, a carrier will not undergo inspection unless the Director determines that a failure to inspect will present a threat of introduction of communicable diseases into the United States, as may exist when the carrier has on board individual(s) reportable in accordance with § 71.21 or meets the circumstances described in §71.42. Carriers not subject to inspection under this section will be subject to sanitary inspection under § 71.41 of this part.

(b) The Director may require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease. The Director may issue a controlled free pratique to the carrier stipulating what measures are to be met, but such issuance does not prevent the periodic boarding of a carrier and the inspection of persons and records to verify that the conditions have been met for granting the pratique.

§ 71.32 Persons, carriers, and things.

(a) Whenever the Director has reason to believe that any arriving person is infected with or has been exposed to any of the communicable diseases listed in paragraph (b) of this section, he/she may detain, isolate, or place the person under surveillance and may order disinfection or disinfestation as he/she considers necessary to prevent the introduction, transmission, or spread of the listed communicable diseases.

(b) The communicable diseases authorizing the application of sanitary, detention, and/or isolation measures under paragraph (a) of this section are: cholera or suspected cholera, diphtheria, infectious tuberculosis, plague, suspected smallpox, yellow fever, or suspected viral hemorrhagic fevers (Lassa, Marburg, Ebola, Congo-Crimean, and others not yet isolated or named).

(c) Whenever the Director has reason to believe that any arriving carrier or article or thing on board the carrier is or may be infected or contaminated with a communicable disease, he/she may require detention, disinsection, disinfection, disinfestation, fumigation, or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases.

§ 71.33 Persons: Isolation and surveillance.

(a) Persons held in isolation under this subpart may be held in facilities suitable for isolation and treatment.

(b) The Director may require isolation where surveillance is authorized in this subpart whenever the Director considers the risk of transmission of infection to be exceptionally serious.

(c) Every person who is placed under surveillance by authority of this subpart shall, during the period of surveillance:

(1) Give information relative to his/her health and his/her intended destination and report, in person or by telephone, to the local health officer having jurisdiction over the areas to be visited, and report for medical examinations as may be required;

(2) Upon arrival at any address other than that stated as the intended destination when placed under surveillance, or prior to departure from the United States, inform, in person or by telephone, the health officer serving the health jurisdiction from which he/she is departing.

(d) From time to time the Director may, in accordance with section 322 of the Public Health Service Act, enter into agreements with public or private medical or hospital facilities for providing care and treatment for persons detained under this part.

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[50 FR 1519, Jan. 11, 1985; 50 FR 3910, Jan. 29, 1985]

§ 71.34 Carriers of U.S. military services.

(a) Carriers belonging to or operated by the military services of the United States may be exempted from inspection if the Director is satisfied that

they have complied with regulations of the military services which also meet the requirements of the regulations in this part. (For applicable regulations of the military services, see Army Regulation No. 40-12, Air Force Regulation No. 161-4, Secretary of the Navy Instruction 6210.2, and Coast Guard Commandant Instruction 6210.2).

(b) Notwithstanding exemption from inspection of carriers under this section, animals or articles on board shall be required to comply with the applicable requirements of Subpart F of this part.

§ 71.35 Report of death or illness on carrier during stay in port.

The master of any carrier at a U.S. port shall report immediately to the quarantine station at or nearest the port the occurrence, on board, of any death or any ill person among passengers or crew.

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Subpart E—Requirements Upon Arrival at U.S. Ports: Sanitary Inspection

§ 71.41 General provisions.

Carriers arriving at a U.S. port from a foreign area shall be subject to a sanitary inspection to determine whether there exists rodent, insect, or other vermin infestation, contaminated food or water, or other insanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable disease.

§ 71.42 Disinfection of imports.

When the cargo manifest of a carrier lists articles which may require disinfection under the provisions of this part, the Director shall disinfect them on board or request the appropriate customs officer to keep the articles separated from the other cargo pending appropriate disposition.

§ 71.43 Exemption for mails.

Except to the extent that mail contains any article or thing subject to restrictions under Subpart F of this part, nothing in the regulations in this part shall render liable to detention, disinfection, or destruction any mail conveyed under the authority of the postal administration of the United States or of any other Government.

§ 71.44 Disinsection of aircraft.

(a) The Director may require disinsection of an aircraft if it has left a foreign area that is infected with insect-borne communicable disease and the aircraft is suspected of harboring insects of public health importance.

(b) Disinsection shall be the responsibility of the air carrier or, in the case of aircraft not for hire, the pilot in command, and shall be subject to monitoring by the Director.

(c) Disinsection of the aircraft shall be accomplished immediately after landing and blocking.

(1) The cargo compartment shall be disinsected before the mail, baggage, and other cargo are discharged.

(2) The rest of the aircraft shall be disinsected after passengers and crew deplane.

(d) Disinsection shall be performed with an approved insecticide in accordance with the manufacturer's instructions. The current list of approved insecticides and sources may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, Georgia 30333.

§ 71.45 Food, potable water, and waste U.S. seaports and airports.

(a) Every seaport and airport shall be provided with a supply of potable water from a watering point approved by the Commissioner of Food and Drugs, Food and Drug Administration, in accordance with standards established in Title 21, Code of Federal Regulations, Parts 1240 and 1250.

(b) All food and potable water taken on board a ship or aircraft at any seaport or airport intended for human consumption thereon shall be obtained from sources approved in accordance with regulations cited in paragraph (a) of this section.

(c) Aircraft inbound or outbound on an international voyage shall not discharge over the United States any excrement, or waste water or other polluting materials. Arriving aircraft shall discharge such matter only at servicing areas approved under regulations cited in paragraph (a) of this section.

§ 71.46 Issuance of Deratting Certificates and Deratting Exemption Certificates.

Valid Deratting Certificates or Deratting Exemption Certificates are not required for ships to enter a U.S. seaport. In accordance with Article 17 of the International Health Regulations, the Public Health Service may perform rodent infestation inspections and issue Deratting Certificates and Deratting Exemption Certificates.

§ 71.47 Special provisions relating to airports: Office and isolation facilities.

Each U.S. airport which receives international traffic shall provide without cost to the Government suitable office, isolation, and other exclusive space for carrying out the Federal responsibilities under this part.

§ 71.48 Carriers in intercoastal and interstate traffic.

Carriers, on an international voyage, which are in traffic between U.S. ports, shall be subject to inspection as described in §§ 71.31 and 71.41 when there occurs on board, among passengers or crew, any death, or any ill person, or when illness is suspected to be caused by insanitary conditions.

Subpart F—Importations

§ 71.51 Dogs and cats.

(a) *Definitions.*

As used in this section the term:

"Cat" means all domestic cats.

"Confinement" means restriction of a dog or cat to a building or other enclosure at a U.S. port, en route to destination and at destination, in isolation from other animals and from persons except for contact necessary for its care or, if the dog or cat is allowed out of the enclosure, muzzling and keeping it on a leash.

"Dog" means all domestic dogs.

"Owner" means owner or agent.

"Valid rabies vaccination certificate" means a certificate which was issued for a dog not less than 3 months of age at the time of vaccination and which:

(1) Identifies a dog on the basis of breed, sex, age, color, markings, and other identifying information.

(2) Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port.

(3) Specifies a date of expiration which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port.

(4) Bears the signature of a licensed veterinarian.

(b) *General requirements for admission of dogs and cats*—(1) *Inspection by Director.* The Director shall inspect all dogs and cats which arrive at a U.S. port, and admit only those dogs and cats which show no signs of communicable disease as defined in § 71.1.

(2) *Examination by veterinarian and confinement of dogs and cats.* When, upon inspection, a dog or cat does not appear to be in good health on arrival (e.g., it has symptoms such as emaciation, lesions of the skin, nervous system disturbances, jaundice, or diarrhea), the Director may require prompt confinement and give the owner an opportunity to arrange for a licensed veterinarian to examine the animal and give or arrange for any tests or treatment indicated. The Director will consider the findings of the examination and tests in determining whether or not the dog or cat may have a communicable disease. The owner shall bear the expense of the examination, tests, and treatment. When it is necessary to detain a dog or cat pending determination of its admissibility, the owner shall provide confinement facilities which in the judgment of the Director will afford protection against any communicable disease. The owner shall bear the expense of confinement. Confinement shall be subject to conditions specified by the Director to protect the public health.

(3) *Record of sickness or death of dogs and cats and requirements for ex-*

posed animals. (i) The carrier responsible for the care of dogs and cats shall maintain a record of sickness or death of animals en route to the United States and shall submit the record to the quarantine station at the U.S. port upon arrival. Dogs or cats which have become sick while en route or are dead on arrival shall be separated from other animals as soon as the sickness or death is discovered, and shall be held in confinement pending any necessary examination as determined by the Director.

(ii) When, upon inspection, a dog or cat appears healthy but, during shipment, has been exposed to a sick or dead animal suspected of having a communicable disease, the exposed dog or cat shall be admitted only if examination or tests made on arrival reveal no evidence that the animal may be infected with a communicable disease. The provisions of paragraph (b)(2) of this section shall be applicable to the examination or tests.

(4) *Sanitation.* When the Director finds that the cages or other containers of dogs or cats arriving in the United States are in an insanitary or other condition that may constitute a communicable disease hazard, the dogs or cats shall not be admitted in such containers unless the owner has the containers cleaned and disinfected.

(c) *Rabies vaccination requirements for dogs.* (1) A valid rabies vaccination certificate is required at a U.S. port for admission of a dog unless the owner submits evidence satisfactory to the Director that:

(i) If a dog is less than 6 months of age, it has been only in a country determined by the Director to be rabies-free (a current list of rabies-free countries may be obtained from the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, Georgia 30333); or

(ii) If a dog is 6 months of age or older, for the 6 months before arrival, it has been only in a country determined by the Director to be rabies-free; or

(iii) The dog is to be taken to a research facility to be used for research purposes and vaccination would interfere with its use for such purposes.

(2) Regardless of the provisions of paragraph (c)(1) of this section, the Director may authorize admission as follows:

(i) If the date of vaccination shown on the vaccination certificate is less than 30 days before the date of arrival, the dog may be admitted, but must be confined until at least 30 days have elapsed since the date of vaccination;

(ii) If the dog is less than 3 months of age, it may be admitted, but must be confined until vaccinated against rabies at 3 months of age and for at least 30 days after the date of vaccination;

(iii) If the dog is 3 months of age or older, it may be admitted, but must be confined until it is vaccinated against rabies. The dog must be vaccinated within 4 days after arrival at destination but no more than 10 days after arrival at a U.S. port. It must be kept in confinement for at least 30 days after the date of vaccination.

(3) When a dog is admitted under paragraph (c)(2) of this section, the Director shall notify the health department or other appropriate agency having jurisdiction at the point of destination and shall provide the address of the specified place of confinement and other pertinent information to facilitate surveillance and other appropriate action.

(d) *Certification requirements.* The owner shall submit such certification regarding confinement and vaccination prescribed under this section as may be required by the Director.

(e) *Additional requirements for the importation of dogs and cats.* Dogs and cats shall be subject to such additional requirements as may be deemed necessary by the Director or to exclusion if coming from areas which the Director has determined to have high rates of rabies.

(f) *Requirements for dogs and cats in transit.* The provisions of this section shall apply to dogs and cats transported through the United States from one foreign country to another, except as provided below:

(1) Dogs and cats that appear healthy, but have been exposed to a sick or dead animal suspected of having a communicable disease, need not undergo examination or tests as

provided in paragraph (b)(3) of this section if the Director determines that the conditions under which they are being transported will afford adequate protection against introduction of communicable disease.

(2) Rabies vaccination is not required for dogs that are transported by aircraft or ship and retained in custody of the carrier under conditions that would prevent transmission of rabies.

(g) *Disposal of excluded dogs and cats.* A dog or cat excluded from the United States under the regulations in this part shall be exported or destroyed. Pending exportation, it shall be detained at the owner's expense in the custody of the U.S. Customs Service at the U.S. port.

(Approved by the Office of Management and Budget under control number 0920-0134)

§ 71.52 Turtles, tortoises, and terrapins.

(a) *Definitions.*

As used in this section the term:

"Turtles" includes all animals commonly known as turtles, tortoises, terrapins, and all other animals of the order *Testudinata*, class *Reptilia*, except marine species (Families *Dermochelidae* and *Cheloniidae*).

(b) *Importation; general prohibition.* Except as otherwise provided in this section, live turtles with a carapace length of less than 4 inches and viable turtle eggs may not be imported into the United States.

(c) *Exceptions.* (1) Live turtles with a carapace length of less than 4 inches and viable turtle eggs may be imported into the United States, provided that such importation is not in connection with a business, and the importation is limited to lots of fewer than seven live turtles or fewer than seven viable turtle eggs, or any combinations of such turtles and turtle eggs totaling fewer than seven, for any entry.

(2) Seven or more live turtles with a carapace length of less than 4 inches, or seven or more viable turtle eggs or any combination of turtles and turtle eggs totaling seven or more, may be imported into the United States for bona fide scientific or educational purposes or for exhibition when accompanied by a permit issued by the Director.

(3) The requirements in paragraphs (c)(1) and (c)(2) of this section shall not apply to the eggs of marine turtles excluded from these regulations under § 71.52(a).

(d) *Application for permits.* Applications for permits to import turtles, as set forth in paragraph (c)(2) of this section, shall be made by letter to the Director, and shall contain, identify, or describe, the name and address of the applicant, the number of specimens, and the common and scientific names of each species to be imported, the holding facilities, the intended use of the turtles following their importation, the precautions to be undertaken to prevent infection of members of the public with *Salmonella* and *Arizona* bacteria, and any other information and assurances the Director may require.

(e) *Criteria for issuance of permits.* A permit may be issued upon a determination that the holder of the permit will isolate or otherwise confine the turtles and will take such other precautions as may be determined by the Director to be necessary to prevent infection of members of the public with *Salmonella* and *Arizona* bacteria and on condition that the holder of the permit will provide such reports as the Director may require.

(f) *Interstate Regulations.* Upon admission at a U.S. Port, turtles and viable turtle eggs become subject to Food and Drug Administration Regulations (21 CFR 1240.62) regarding general prohibition.

(g) *Other permits.* Permits to import certain species of turtles may be required under other Federal regulations (50 CFR Parts 17 and 23) protecting such species.

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§ 71.53 Nonhuman primates.

(a) *Definitions.*

As used in this section the term:

"Importer" means any person or corporation, partnership, or other organization, receiving live nonhuman primates from a foreign country within a

period of 31 days, beginning with the importation date, whether or not the primates were held for part of the period at another location. The term "importer" includes the original importer and any other person or organization receiving imported primates within the 31-day period.

"Nonhuman primates" means all nonhuman members of the Order Primates, including, but not limited to, animals commonly known as monkeys, chimpanzees, orangutans, gorillas, gibbons, apes, baboons, marmosets, tamarin, lemurs, and lorises.

(b) *General prohibition.* No person or organization may import live nonhuman primates into the United States unless registered as an importer in accordance with applicable provisions of this section.

(c) *Uses for which nonhuman primates may be imported and distributed.* Live nonhuman primates may be imported into the United States and sold, resold, or otherwise distributed only for bona fide scientific, educational, or exhibition purposes. The importation of nonhuman primates for use in breeding colonies is also permitted provided that all offspring will be used only for scientific, educational, or exhibition purposes. The maintenance of nonhuman primates as pets, hobby, or an avocation with occasional display to the general public is not a permissible use.

(d) *Registration of importers.* (1) Importers of nonhuman primates shall register with the Director in a manner prescribed by the Director.

(2) Documentary evidence that an importer will use all nonhuman primates solely for the permitted purposes is required.

(3) Registration shall inlcude certification that the nonhuman primates will not be shipped, sold, or otherwise transferred to other persons or organizations without adequate proof that the primates will be used only for the permitted purposes.

(4) Registration shall be for 2 years, effective the date the application for registration is approved by the Director.

(5) Registration may be renewed by filing a registration application form with the Director not less than 30 days nor more than 60 days before expiration of the current registration.

(e) *Recordkeeping and reporting requirement for registered importers.* (1) Importers shall maintain records on each shipment of imported nonhuman primates received. The record on each shipment shall include the number of primates received, species, country of origin, date of importation, the number of primates in the shipment that die within 90 days after receipt, and cause(s) of deaths. If any primates in the shipment are sold or otherwise distributed within 90 days after receipt, the record shall include the number of primates in each shipment or sale, the dates of each shipment or sale, and the identity of the recipients. In addition, the record shall contain copies of documents that were presented to the importer to establish that the recipient would use the primates solely for the permitted purposes. The records shall be maintained in an organized manner in a central location at or in close proximity to the importer's primate holding facility. The records shall be maintained for a period of 3 years and shall be available for inspection by the Director at any time.

(2) Importers shall report to the Director by telephone within 24 hours the occurrence of any illness in nonhuman primates that is suspected of being yellow fever, monkeypox, or Marburg/Ebola disease.

(3) Importers also shall report to the Director by telephone within 24 hours the occurrence of illness in any member of their staff suspected of having an infectious disease acquired from nonhuman primates.

(f) *Disease control measures.* Upon receipt of evidence of exposure of nonhuman primates to a communicable disease that may constitute a threat to public health, the Director may provide for or require examination, treatment, detention, isolation, seizure, or destruction of exposed animals. Any measures required shall be at the owner's expense.

(g) *Disposal of excluded nonhuman primates.* Nonhuman primate(s) excluded from the United States by provisions of this section shall, at the owner's option and expense, be export-

ed, destroyed, or given to a scientific, educational, or exhibition facility under arrangements approved by the Director. If the owner fails to dispose of the nonhuman primate by one of the approved options or fails to select a method of disposal within 7 days, the Director will select the method of disposal. Pending disposal, the nonhuman primate(s) shall be detained at the owner's expense in custody of the U.S. Customs Service at the U.S. port.

(h) *Revocation of an importer's registration.* (1) An importer's registration may be revoked by the Director, upon notice to the importer holding such registration, if the Director determines that the importer has failed to comply with any applicable provisions of this section. The notice shall contain a statement of the grounds upon which the revocation is based.

(2) The importer may file an answer within 20 days after receipt of the notice. Answers shall admit or deny specifically, and in detail, each allegation in the notice. Allegations in the notice not denied by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the importer to file an answer within 20 days after receipt of the notice may be deemed an admission of all allegations of fact recited in the notice.

(3) The importer shall be entitled to a hearing with respect to the revocation upon filing a written request, either in the answer or in a separate document, with the Director within 20 days after the effective date of revocation. Failure to request a hearing shall be deemed a waiver of hearing and as consent to the submission of the case to the Director for decision based on the written record. The failure both to file an answer and to request a hearing shall be deemed to constitute consent to the making of a decision on the basis of available information.

(4) As soon as practicable after the completion of any hearing conducted pursuant to the provisions of this section, the Director shall render a final decision. A copy of such decision shall be served on the importer.

(5) An importer's registration which has been revoked may be reinstated by the Director upon inspection, examination of records, conference with the importer, and receipt of information and assurances of compliance with the requirements of this section.

(i) *Other permits.* In addition to the requirements under this section, permits to import certain species of nonhuman primates may also be required under other Federal regulations (50 CFR Parts 17 and 23) protecting such species.

(Approved by the Office of Management and Budget under control number 0920-0134)

§ 71.54 Etiological agents, hosts, and vectors.

(a) A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

§ 71.55 Dead bodies.

The remains of a person who died of a communicable disease listed in § 71.32(b) may not be brought into a U.S. port unless the body is (a) properly embalmed and placed in a hermetically sealed casket, (b) cremated, or (c) accompanied by a permit issued by the Director.

PART 72—INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS [1]

Sec.

72.1 Definitions.
72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

[1] The requirements of this part are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate

Continued

72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.
72.4 Notice of delivery; failure to receive.
72.5 Requirements; variations.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 42 U.S.C. 216; sec. 361, 58 Stat. 703, (42 U.S.C. 264).

SOURCE: 45 FR 48627, July 21, 1980, unless otherwise noted.

§ 72.1 Definitions.

As used in this part:

"Biological product" means a biological product prepared and manufactured in accordance with the provisions of 9 CFR Parts 102-104 and 21 CFR Parts 312 and 600-680 and which, in accordance with such provisions, may be shipped in interstate traffic.

"Diagnostic specimen" means any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

"Etiologic agent" means a viable microorganism or its toxin which causes, or may cause, human disease.

"Interstate traffic" means the movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possession, (a) from a point of origin in any State or possession to a point of destination in any other State or possession, or (b) between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

§ 72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products which such person reasonably believes may contain an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

§ 72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.

Notwithstanding the provisions of § 72.2, no person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material (other than biological products) known to contain, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is packaged, labeled, and shipped in accordance with the requirements specified in paragraphs (a) through (f) of this section:

BACTERIAL AGENTS

Acinetobacter calcoaceticus.
Actinobacillus—all species.
Actinomycetaceae—all members.
Aeromonas hydrophila.
Arachnia propionica.
Arizona hinshawii—all serotypes.
Bacillus anthracis.
Bacteroides spp.
Bartonella—all species.
Bordetella—all species.
Borrelia recurrentis, B. vincenti.
Brucella—all species.
Campylobacter (Vibrio) foetus, C. (Vibrio) jejuni.
Chlamydia psittaci, C. trachomatis.
Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani.
Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale.
Edwarsiella tarda.
Erysipelothrix insidiosa.
Escherichia coli, all enteropathogenic serotypes.
Francisella (Pasteurella) Tularensis.
Haemophilus ducreyi, H. influenzae.
Klebsiella—all species and all serotypes.
Legionella—all species and all Legionella like organisms.
Leptospira interrogans—all serovars.
Listeria—all species.
Mimae polymorpha.
Moraxella—all species.
Mycobacterium—all species.
Mycoplasma—all species.
Neisseria gonorrhoeae, N. meningitidis.
Nocardia asteroides.
Pasteurella—all species.

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traffic prescribed by the Department of Transportation and other agencies of the Federal Government.

Plesiomonas shigelloides.
Proteus—all species.
Pseudomonas mallei.
Pseudomonas pseudomallei.
Salmonella—all species and all serotypes.
Shigella—all species and all serotypes.
Sphaerophorus necrophorus.
Staphylococcus aureus.
Streptobacillus moniliformis.
Streptococcus pneumoniae.
Streptococcus pyogenes.
Treponema careteum, T. pallidum, and *T. pertenue.*
Vibrio cholerae, V. parahemolyticus.
Yersinia (*Pasteurella*) *pestis, Y. enterocolitica.*

FUNGAL AGENTS

Blastomyces dermatitidis.
Coccidioides immitis.
Cryptococcus neoformans.
Histoplasma capsulatum.
Paracoccidioides brasiliensis.

VIRAL AND RICKETTSIAL AGENTS

Adenoviruses—human—all types.
Arboviruses—all types.
Coxiella burnetti.
Coxsackie A and B viruses—all types.
Creutzfeldt—Jacob agent.
Cytomegaloviruses.
Dengue viruses—all types.
Ebola virus.
Echoviruses—all types.
Encephalomyocarditis virus.
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB).
Herpesvirus—all members.
Infectious bronchitis-like virus.
Influenza viruses—all types.
Kuru agent.
Lassa virus.
Lymphocytic choriomeningitis virus.
Marburg virus.
Measles virus.
Mumps virus.
Parainfluenza viruses—all types.
Polioviruses—all types.
Poxviruses—all members.
Rabies virus—all strains.
Reoviruses—all types.
Respiratory syncytial virus.
Rhinoviruses—all types.
Rickettsia—all species.
Rochalimaea quintana.
Rotaviruses—all types.
Rubella virus.
Simian virus 40.
Tick-borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.
Vaccinia virus.
Varicella virus.
Variola major and Variola minor viruses.
Vesicular stomatis viruses—all types.
White pox viruses.
Yellow fever virus.[2]

(a) *Volume not exceeding 50 ml.* Material shall be placed in a securely closed, watertight container (primary container (test tube, vial, etc.)) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

(b) *Volume greater than 50 ml.* Packaging of material in volumes of 50 ml. or more shall comply with requirements specified in paragraph (a) of this section. In addition, a shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. Single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be placed in a single, secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

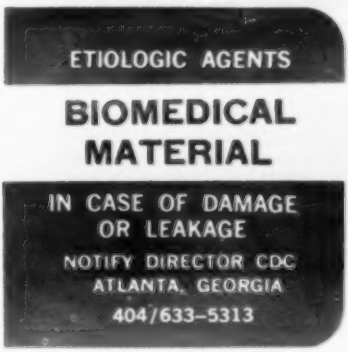
(c) *Dry ice.* If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice

[2] This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be packaged in accordance with the requirements contained in this part.

is used between the secondary container and the outer shipping container, the shock absorbent material shall be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

(d)(1) The outer shipping container of all materials containing etiologic agents transported in interstate traffic must bear a label as illustrated and described below:

STANDARD FORM 420 JUNE 1973
PRESCRIBED BY DEPT HEW (4.2 CFR) 420-101



(2) The color of material on which the label is printed must be white, the symbol red, and the printing in red or white as illustrated.

(3) The label must be a rectangle measuring 51 millimeters (mm) (2 inches) high by 102.5 mm (4 inches) long.

(4) The red symbol measuring 38 mm (1½ inches) in diameter must be centered in a white square measuring 51 mm (2 inches) on each side.

(5) Type size of the letters of label shall be as follows:

Etiologic agents—10 pt. rev.
Biomedical material—14 pt.
In case of damage or leakage—10 pt. rev.
Notify Director CDC, Atlanta, Georgia—8 pt. rev.
404-633-5313—10 pt. rev.

(e) *Damaged packages.* The carrier shall promptly, upon discovery of evidence of leakage or any other damage to packages bearing an Etiologic Agents/Biomedical Material label, isolate the package and notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333, by telephone: (404) 633-5313. The carrier shall also notify the sender.

(f) *Registered mail or equivalent system.* Transportation of the following etiologic agents shall be by registered mail or an equivalent system which requires or provides for sending notification of receipt to the sender immediately upon delivery:

Coccidioides immitis.
Ebola virus.
Francisella (Pasteurella) tularensis.
Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
Herpesvirus simiae (B virus).
Histoplasma capsulatum.
Lassa virus.
Marburg virus.
Pseudomonas mallei.
Pseudomonas pseudomallei.
Tick-borne encephalitis virus complex including, but not limited to, Russian spring-summer encephalitis, Kyasanur

forest disease, Omsk Hemorrhagic fever, and Central European encephalitis viruses, Variola minor, and Variola major.

Variola major, Variola minor, and Whitepox viruses.

Yersinia (Pasteurella) pestis.[1]

§ 72.4 Notice of delivery; failure to receive.

When notice of delivery of materials known to contain or reasonably believed to contain etiologic agents listed in § 72.3(f) is not received by the sender within 5 days following anticipated delivery of the package, the sender shall notify the Director, Center for Disease Control, 1600 Clifton Road, NE., Atlanta, GA 30333 (telephone (404) 633-5313).

§ 72.5 Requirements; variations.

The Director, Center for Disease Control, may approve variations from the requirements of this section if, upon review and evaluation, it is found that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this section and such findings are made a matter of official record.

PART 74—[RESERVED]

PART 75—STANDARDS FOR THE ACCREDITATION OF EDUCATIONAL PROGRAMS FOR AND THE CREDENTIALING OF RADIOLOGIC PERSONNEL

Sec.

75.1 Background and purpose.
75.2 Definitions.
75.3 Applicability.

APPENDIX A—STANDARDS FOR ACCREDITATION OF EDUCATION PROGRAMS FOR RADIOGRAPHERS

APPENDIX B—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL HYGIENISTS

APPENDIX C—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL ASSISTANTS

APPENDIX D—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR NUCLEAR MEDICINE TECHNOLOGISTS

APPENDIX E—STANDARDS FOR ACCREDITATION OF EDUCATION PROGRAMS FOR RADIATION THERAPY TECHNOLOGISTS

APPENDIX F—STANDARDS FOR LICENSING RADIOGRAPHERS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIATION THERAPY TECHNOLOGISTS

APPENDIX G—STANDARDS FOR LICENSING DENTAL HYGIENISTS AND DENTAL ASSISTANTS IN DENTAL RADIOGRAPHY

AUTHORITY: Sec. 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, Pub. L. 97-35, 95 Stat. 599-600 (42 U.S.C. 10004).

SOURCE: 50 FR 50717, Dec. 11, 1985, unless otherwise noted.

§ 75.1 Background and purpose.

(a) The purpose of these regulations is to implement the provisions of section 979 of the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10004, which requires the establishment by the Secretary of Health and Human Services of standards for the accreditation of programs for the education of certain persons who administer radiologic procedures and for the credentialing of such persons.

(b) Section 979 requires the Secretary, after consultation with specified Federal agencies, appropriate agencies of States, and appropriate professional organizations, to promulgate by regulation the minimum standards described above. These standards distinguish between the occupations of (1) radiographer, (2) dental hygienist, (3) dental assistant, (4) nuclear medicine technologist, and (5) radiation therapy technologist. In the interest of public safety and to prevent the hazards of improper use of medical radiation identified by Congress in its determination of the need for standards, the Secretary is also authorized to prepare standards for other occupational groups utilizing ionizing and non-ionizing radiation as he/she finds appropriate. However, the standards set out below are limited to the five occupational groups listed above, utilizing ionizing radiation. Nothing in these accreditation standards is intended to

[1] This list may be revised from time to time by Notice published in the FEDERAL REGISTER to identify additional agents which must be transported in accordance with requirements contained in § 72.3(f).

discriminate against proprietary schools.

§ 75.2 Definitions.

All terms not defined herein shall have the meaning given them in the Act. As used in this part:

"Accreditation," as applied to an educational program, means recognition, by a State government or by a nongovernmental agency or association, of a specialized program of study as meeting or exceeding certain established qualifications and educational standards. As applied to a health care or educational institution, "accreditation" means recognition, by a State government or by a nongovernmental agency or association, of the institution as meeting or exceeding certain established standards or criteria for that type of institution.

"Act" means the Consumer-Patient Radiation Health and Safety Act of 1981, 42 U.S.C. 10001–10008.

"Continuing competency" means the maintenance of knowledge and skills and/or demonstrated performance that are adequate and relevant to professional practice needs.

"Credentialing" means any process whereby a State Government or nongovernmental agency or association grants recognition to an individual who meets certain predetermined qualifications.

"Dental hygienist" means a person licensed by the State as a dental hygienist.

"Dental assistant" means a person other than a dental hygienist who assists a dentist in the care of patients.

"Educational program" means a set of formally structured activities designed to provide students with the knowledge and skills necessary to enter an occupation, with evaluation of student performance according to predetermined objectives.

"Energized laboratory" means any facility which contains equipment that generates ionizing radiation. This does not include facilities for training students when the equipment is not powered to emit ionizing radiation, e.g., practice in setting controls and positioning of patients.

"Formal training" means training or education, including either didactic or clinical practicum or both, which has a specified objective, planned activities for students, and suitable methods for measuring student attainment, and which is offered, sponsored, or approved by an organization or institution which is able to meet or enforce these criteria.

"Ionizing radiation" means any electromagnetic or particulate radiation (X-rays, gamma rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles) which interacts with atoms to produce ion pairs in matter.

"Licensed practitioner" means a licensed doctor of medicine, osteopathy, dentistry, podiatry, or chiropractic.

"Licensure" means the process by which an agency of State government grants permission to persons meeting predetermined qualifications to engage in an occupation.

"Nuclear medicine technologist" means a person other than a licensed practitioner who prepares and administers radio-pharmaceuticals to human beings and conducts *in vivo* or *in vitro* detection and measurement of radioactivity for medical purposes.

"Permit" means an authorization issued by a State for specific tasks or practices rather than the entire scope of practice in an occupation.

"Radiation therapy technologist" means a person other than a licensed practitioner who utilizes ionizing radiation-generating equipment for therapeutic purposes on human subjects.

"Radiographer" means an individual other than a licensed practitioner who (1) performs, may be called upon to perform, or who is licensed to perform a comprehensive scope of diagnostic radiologic procedures employing equipment which emits ionizing radiation, and (2) is delegated or exercises responsibility for the operation of radiation-generating equipment, the shielding of patient and staff from unnecessary radiation, the appropriate exposure of radiographs, or other procedures which contribute to any significant extent to the site or dosage of ionizing radiation to which a patient is exposed. Radiographers are distinguished from personnel whose use of diagnostic procedures is limited to a few specific body sites and/or stand-

ard procedures, from those personnel in other clinical specialties who may occasionally be called upon to assist in diagnostic radiology, and from those technicians or assistants whose activities do not, to any significant degree, determine the site or dosage of radiation to which a patient is exposed.

"Radiologist" means a physician certified in radiology by the American Board of Radiology or the American Osteopathic Board of Radiology.

§ 75.3 **Applicability.**

(a) *Federal Government.* Except as provided in section 983 of the Act, the credentialing standards set out in the Appendixes to this part apply to those individuals who administer or propose to administer radiologic procedures, in each department, agency and instrumentality of the Federal Government as follows:

(1) "Radiographer Standards" apply to all individuals who are radiographers as defined in § 75.2 and who are not practitioners excepted by the Act.

(2) "Nuclear Medicine Technologist Standards" apply to all individuals who are nuclear medicine technologists as defined in § 75.2, who perform *in vivo* nuclear medicine procedures, and who are not practitioners excepted by the Act. For purposes of this Act, any administration of radiopharmaceuticals to human beings is considered an *in vivo* procedure.

(3) "Radiation Therapy Technologist Standards" apply to all individuals who perform radiation therapy and who are not practitioners excepted by the Act.

(4) "Dental Hygienist Standards" apply to all dental hygienists who perform dental radiography.

(5) "Dental Assistant Standards" apply to all dental assistants who perform dental radiography.

(6) The following persons are deemed to have met the requirements of these standards:

(i) Persons employed by the Federal government as radiologic personnel prior to the effective date of this regulation and who show evidence of current or fully satisfactory performance or certification of such from a licensed practitioner;

(ii) Uniformed military personnel who receive radiologic training from or through the Armed Forces of the United States and who meet standards established by the Department of Defense or components thereof, provided that those standards are determined by such Department or component to offer equivalent protection of patient health and safety;

(iii) Foreign national employed by the Federal government in positions outside of the United States who show evidence of training, experience, and competence determined by the employing agency to be equally protective of patients health and safety; and

(iv) Persons first employed by the Federal government as radiologic personnel after the effective date of this regulation who (*a*) received training from institutions in a State or foreign jurisdiction which did not accredit training in that particular field at the time of graduation, or (*b*) practiced in a State or foreign jurisdiction which did not license that particular field or which did not allow special eligibility to take a licensure examination for those who did not graduate from an accredited educational program; provided that such persons show evidence of training, experience, and competence determined by the Office of Personnel Management or the employing agency to be equally protective of patient health and safety.

(7) The following persons are exempted from these standards:

(i) Persons who are trained to perform, or perform, covered radiologic procedures in emergency situations which preclude use of fully qualified personnel; and

(ii) Students in approved training programs.

(8) A department, agency, or instrumentality of the Federal government may, after consultation with the Secretary, use alternative criteria which it determines would offer equivalent protection of patient health and safety.

(b) *States.* The States may, but are not required to, adopt standards for accreditation and credentialing that are consistent with the standards set out in the Appendixes to this part.

APPENDIX A—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIOGRAPHERS

A. Description of the Profession

The radiographer shall perform effectively by:

1. Applying knowledge of the principles of radiation protection for the patient, self, and others.

2. Applying knowledge of anatomy, positioning, and radiographic techniques to accurately demonstrate anatomical structures on a radiograph.

3. Determining exposure factors to achieve optimum radiographic technique with a minimum of radiation exposure to the patient.

4. Examining radiographs for the purpose of evaluating technique, positioning, and other pertinent technical qualities.

5. Exercising discretion and judgment in the performance of medical imaging procedures.

6. Providing patient care essential to radiologic procedures.

7. Recognizing emergency patient conditions and initiating lifesaving first aid.

B. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities;

(b) Hospitals;

(c) Medical schools;

(d) Postsecondary vocational/technical schools and institutions; and

(e) Other acceptable institutions which meet comparable standards.

3. The sponsoring institutions and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affilitate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

C. Instructional Facilities

1. *General.* Appropriate classroom and clinical space, modern equipment, and supplies for supervised education shall be provided.

2. *Laboratory.* Energized laboratories utilized for teaching purposes shall be certified as required for compliance with Federal and/or State radiation safety regulations. The use of laboratories shall be governed by established educational objectives.

3. *Reference Materials.* Adequate up-to-date scientific books, periodicals, and other reference materials related to the curriculum and profession shall be readily accessible to students.

D. Clinical Education

1. The clinical phase of the educational program shall provide an environment for supervised competency-based clinical education and experience and offer a sufficient and well-balanced variety of radiographic examinations and equipment.

2. An acceptable ratio of students to registered technologists shall be maintained in the clinical teaching environment.

3. A clinical instructor(s), who shall be responsible for supervising students according to objectives, shall be identified for each primary clinical education center.

4. The maximum student enrollment shall not exceed the capacity recommended on the basis of volume and variety of radiographic procedures, resources, and personnel available for teaching purposes.

5. In programs where didactic and clinical experience are not provided in the same institution, accreditation shall be given only to the institution responsible for admissions, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the students in the clinical setting are educational. There shall be a uniform contract between the accredited institution and each of its affiliate hospitals, clearly defining the responsibilities and obligations of each.

E. Curriculum

1. The structure of the curriculum shall be based on not less than two calendar years of full-time study or its equivalent.

2. Instruction shall follow a planned outline that includes:

(a) The assignment of appropriate instructional materials;

(b) Classroom presentations, discussions and demonstrations; and

(c) Examinations in the didactic and clinical aspects of the program.

3. All professional courses, including clinical education, must include specific curriculum content that shall include, but shall not be limited to:

(a) Introduction to radiologic technology;

(b) Medical ethics;

(c) Imaging;

(d) Radiographic processing technique;

(e) Human structure and function;

(f) Medical terminology;

(g) Principals of radiographic exposure;
(h) Radiographic procedures;
(i) Principles of radiation protection;
(j) Radiographic film evaluation;
(k) Methods of patient care;
(l) Pathology;
(m) Radiologic physics; and
(n) Radiation biology.

Related subjects added to the professional curriculum shall meet the requirements of the degree-granting institution.

F. Finances

Financial resources for operation for the educational program shall be assured through regular budgets, gifts, grants, endowments, or fees.

G. Faculty

1. *Program Director.* A program director shall be designated who is credentialed in radiography. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiography shall not be adversely affected by educationally unrelated functions.

(a) *Minimum qualifications.* A minimum of two years of professional experience and proficiency in instructing, curriculum design, program planning, and counseling.

(b) *Responsibilities.* (1) The program director, in consultation with the medical director/advisor (G. 2.) shall be responsible for the organization, administration, periodic review, records, continued development, and general policy and effectiveness of the program.

(2) Opportunities for continuing education shall be provided for all faculty members.

2. *Medical Director/Medical Advisor*—(a) *minimum qualifications.* The medical director/medical advisor shall be a qualified radiologist, certified by the American Board of Radiology, or shall possess suitable equivalent qualifications.

(b) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for their achievement.

3. *Instructors.* All instructors shall be qualified through academic preparation and experience to teach the assigned subjects.

H. Students

Admission

(a) Candidates for admission shall satisfy the following minimum requirements: Completion of four years of high school; successful completion of a standard equivalency test; or certification of equivalent education by an organization recognized by the United States Department of Education. Courses in physics, chemistry, biology, algebra, and geometry are strongly recommended.

(b) The number of students enrolled in each class shall be commensurate with the most effective learning and teaching practices and should also be consistent with acceptable student-teacher ratios.

I. Records

Records shall be maintained as dictated by good educational practices.

NOTE: Educational programs accredited by an organization recommended by the United States Department of Education are considered to have met these standards.

APPENDIX B—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL HYGIENISTS

A. Sponsorship

Sponsorship must be by an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. The formal training in dental radiography may be a part of a total program of dental hygiene education accredited by an organization recognized by the United States Department of Education.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental hygiene education programs or the State entity responsible for credentialing dental personnel in radiography.

B. Curriculum

Dental radiography training for dental hygienists must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental hygienists to understand the critical nature of the radiological procedures they perform and of the judg-

ments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: Interaction of ionizing radiation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: Sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry; patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that Dental Hygienists have the opportunity to develop competence in making radiographs. Faculty supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice where there is not direct supervision by faculty.

—Dental hygienists must demonstrate knowledge of radiation safety measures before making radiographs and, where possible, should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity which approved the training program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment must be available and of a quality that

assures that films will not be damaged or lost.

F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards. Under existing licensure provisions in all States, becoming a dental hygienist requires graduation from a dental hygiene education program accredited by an organization recognized by the United States Department of Education. In lieu of this requirement, Alabama accepts graduation from a State-approved preceptorship program.

APPENDIX C—STANDARDS FOR ACCREDITATION OF DENTAL RADIOGRAPHY TRAINING FOR DENTAL ASSISTANTS

A. Sponsorship

Sponsorship must be an entity that assumes primary responsibility for the planning and conduct of competency-based didactic and clinical training in dental radiography.

1. This responsibility must include: Defining the curriculum in terms of program goals, instructional objectives, learning experiences designed to achieve goals and objectives, and evaluation procedures to assess attainment of goals and objectives; coordinating classroom teaching and supervised clinical experiences; appointing faculty; receiving and processing applications for admission; and granting documents of successful completion of the program.

2. Dental radiography training may be freestanding (as a continuing education course offered by State dental/dental auxiliary societies, or by dental/dental auxiliary education programs); or be a part of an educational program in dental assisting. Such dental assisting education programs may be accredited by an organization recognized by the United States Department of Education; or located in a school accredited by an institutional accrediting agency recognized by the the United States Department of Education or approved by the State agency responsible for secondary and postsecondary education, or approved by a Federal agency conducting dental assistant education in that Agency.

3. The sponsoring entity and the dental radiography training must be approved by the State entity responsible for approving dental assisting education programs, or the State entity responsible for credentialing dental personnel in radiography.

B. Curriculum

Dental radiography training for dental assistants must provide sufficient content and instructional time to assure competent performance.

1. The dental radiography curriculum content and learning experiences must include the theoretical aspects of the subject as well as practical application of techniques. The theoretical aspects should provide content necessary for dental assistants to understand the critical nature of the radiological procedures they perform and of the judgments they make as related to patient and operator radiation safety.

2. The dental radiography curriculum must include content in seven areas: radiation physics; radiation biology; radiation health, safety, and protection; X-ray films and radiographic film quality; radiographic techniques; darkroom and processing techniques; and film mounting.

—*Radiation Physics.* Curriculum content should include: Historical background; role of radiology in modern dentistry; types of radiation; X-ray production principles; operation of X-ray equipment; properties of X-radiation; and X-radiation units, detection and monitoring devices.

—*Radiation Biology.* Curriculum content should include: interaction of ionizing radiation with cells, tissues, and matter; factors influencing biological response of cells and tissues to ionizing radiation; somatic and genetic effects of radiation exposure; and cumulative effects of X-radiation and latent period.

—*Radiation Health, Safety, and Protection.* Curriculum content should include: sources and types of radiation exposure; public health implications and public concerns; principles of radiological health including collimation and filtration; radiation protection methods in the dental office; necessity for high diagnostic yield with a reduction of X-radiation exposure; and monitoring devices.

—*X-ray Films and Radiographic Film Quality.* Curriculum content should include: X-radiation production and scatter; X-ray beam quality and quantity; factors influencing radiographic density, contrast, definition, and distortion; film characteristics; dosage related to film speed; types of films, cassettes, and screens; and film identification systems.

—*Radiographic Techniques.* Curriculum content should include: imagery geometry;

patient positioning; film/film holder positioning; cone positioning and exposure settings for the intraoral paralleling technique, bisecting the angle technique, and techniques for occlusal radiographs; extraoral panoramic techniques; and patient variations that affect the above techniques.

—*Darkroom and Processing Techniques.* Curriculum content should include: Solution chemistry and quality maintenance; darkroom equipment and safe lighting; film processing techniques; automatic film processing; and processing errors.

—*Film Mounting.* Curriculum content should include: anatomical landmarks essential to mounting films; film mounting procedures; and diagnostic quality of radiographs.

3. The curriculum must also include clinical practice assignments.

—Clinical practice assignments must be an integral part of the curriculum so that Dental Assistants have the opportunity to develop competence in making radiographs. The clinical experience may be conducted in the dental office in which the Dental Assistant is employed or is serving an externship. Faculty and/or employing dentist supervision must be provided during a student's radiographic technique experience. Students must demonstrate competence in making diagnostically acceptable radiographs prior to their clinical practice when there is not direct supervision by faculty and/or the employing dentist.

—Dental Assistants must demonstrate knowledge of radiation safety measures before making radiographs, and where possible should demonstrate competence on manikins before making radiographs on patients. Radiographs must be exposed for diagnostic purposes and not solely to demonstrate techniques or obtain experience.

—The clinical experience should provide opportunity to make a variety of radiographs and radiographic surveys, including primary, mixed, and permanent dentitions, as well as edentulous and partially edentulous patients.

C. Student Evaluation

Evaluation procedures must be developed to assess performance and achievement of dental radiography program objectives.

D. Faculty

The dental radiography training must be conducted by faculty who are qualified in the curriculum subject matter.

1. This may include a D.D.S./D.M.D. degree; graduation from an accredited dental assisting or dental hygiene education program with a certificate or an associate or baccalaureate degree; status as a Certified Dental Assistant certified by the Dental Assisting National Board; or recognition as equivalently qualified by the State entity (or Federal agency where appropriate) which approves the educational program in dental radiography.

2. The faculty-to-student ratio must be adequate to achieve the stated objectives of the curriculum.

E. Facilities

Adequate radiographic facilities must be available to permit achievement of the dental radiography training objectives. The design, location, and construction of radiographic facilities must provide optimum protection from X-radiation for patients and operators. Equipment shall meet State and Federal laws related to radiation. Monitoring devices shall be worn by dental personnel. Lead aprons must be placed to protect patients. Safe storage for films must be provided. Darkroom facilities and equipment must be available and of a quality that assures that films will not be damaged or lost.

F. Learning Resources

A wide range of printed materials, instructional aids, and equipment must be available to support instruction. Current specialized reference texts should be provided; and models, replicas, slides, and films which depict current techniques should be available for use in instruction. As appropriate self-instructional materials become available, they should be provided for the student's use.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX D—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR NUCLEAR MEDICINE TECHNOLOGISTS

A. Sponsorship

1. Accreditation will be granted to the institution that assumes primary responsibility for curriculum planning and selection of course content; coordinates classroom teaching and supervised clinical education; appoints faculty to the program; receives and processes applications for admission; and grants the degree or certificate documenting completion of the program.

2. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities;

(b) Hospitals and clinics;
(c) Laboratories;
(d) Medical schools;
(e) Postsecondary vocational/technical schools and institutions; and
(f) Other acceptable institutions which meet comparable standards.

3. The sponsoring institution and affiliate(s) must be accredited by a recognized agency. When the sponsoring institution and affiliate(s) are not so recognized, they may be considered as meeting the requirements of accreditation if the institution meets or exceeds established equivalent standards.

4. Responsibilities of the sponsor and each affiliate for program administration, instruction, supervision, etc., must be carefully described in written affiliation agreements.

B. Curriculum

Instruction must follow a plan which documents:

1. A structured curriculum including clinical education with clearly written syllabi which describe learning objectives and competencies to be achieved. The curriculum shall be based on not less than one calendar year of full-time study or its equivalent.

2. The minimum professional curriculum that includes the following:
(a) Methods of patient care;
(b) Radiation safety and protection;
(c) Nuclear medicine physics;
(d) Radiation physics;
(e) Nuclear instrumentation;
(f) Statistics;
(g) Radionuclide chemistry;
(h) Radiopharmacology;
(i) Departmental organization and function;
(j) Radiation biology;
(k) Nuclear medicine *in vivo* and *in vitro* procedures;
(l) Radionuclide therapy;
(m) Computer applications; and
(n) Clinical practicum.

3. Assignment of appropriate instructional materials.

4. Classroom presentations, discussions, and demonstrations.

5. Supervised practice, experience, and discussions. This shall include the following:
(a) Patient care and patient recordkeeping;
(b) Participation in the quality assurance program;
(c) The preparation, calculation, identification, administration, and disposal of radiopharmaceuticals;
(d) Radiation safety techniques that will minimize radiation exposure to the patient, public, fellow workers, and self;
(e) The performance of an adequate number and variety of imaging and non-imaging procedures; and
(f) Clinical correlation of nuclear medicine procedures.

6. Evaluation of student's knowledge, problem-solving skills, and motor and clinical competencies.

7. The competencies necessary for graduation.

C. Resources

1. The program must have qualified program officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. The following program officials must be identified:

(a) *Program Director*—(1) *Responsibilities.* The program director of the educational program shall have overall responsibility for the organization, administration, periodic review, continued development, and general effectiveness of the program. The director shall provide supervision and coordination to the instructional staff in the academic and clinical phases of the program. Regular visits to the affiliates by the program director must be scheduled.

(2) *Qualifications.* The program director must be a physician or nuclear medicine technologist. The program director must demonstrate proficiency in instruction, curriculum design, program planning, and counseling.

(b) *Medical Director*— (1) *Responsibilities.* The medical director of the program shall provide competent medical direction and shall participate in the clinical instruction. In multiaffiliate programs each clinical affiliate must have a medical director.

(2) *Qualifications.* The medical director must be a physician qualified in the use of radionuclides and a diplomate of the American Board(s) of Nuclear Medicine, or Pathology, or Radiology, or possess suitable equivalent qualifications.

(c) *Clinical Supervisor.* Each clinical affiliate must appoint a clinical supervisor.

(1) *Responsibilities.* The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical affiliate.

(2) *Qualifications.* The clinical supervisor must be a technologist credentialed in nuclear medicine technology.

2. *Instructional Staff* —(a) *Responsibilities.* The instructional staff shall be responsible for instruction in the didactic and/or clinical phases of the program. They shall submit course outlines for each course assigned by the program director; evaluate students and report progress as required by the sponsoring institution; and cooperate with the program director in the periodic review and upgrading of course material.

(b) *Qualifications.* The instructors must be qualified, knowledgeable, and effective in teaching the subjects assigned.

(c) *Instructor-to-student ratio.* The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional development.* Accredited programs shall assure continuing education in the health profession or occupation and ongoing instruction for the faculty in curriculum design and teaching techniques.

3. Financial resoures for continued operation of the educational program must be assured.

4. *Physical Resources.* (a) *General.* Adequate classrooms, laboratories, and other facilities shall be provided.

(b) *Equipment and Supplies.* Modern nuclear medicine equipment, accurately calibrated, in working order, and meeting applicable Federal and State standards, if any, must be available for the full range of diagnostic and therapeutic procedures as outlined in the curriculum.

(c) *Reference Materials.* Reference materials appropriate to the curriculum shall be readily accessible to students.

(d) *Records.* Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources.* Instructional aids such as clinical materials, reference materials, demonstration and other multimedia materials must be provided.

D. Students

Admission Requirements

Persons admitted into nuclear medicine technology programs shall have completed high school or its equivalent. They shall have completed postsecondary courses in the following areas:

(1) Human anatomy and physiology;
(2) Physics;
(3) Mathematics;
(4) Medical terminology;
(5) Oral and written communications;
(6) General chemistry; and
(7) Medical ethics.

Prerequisites may be completed during nuclear medicine training. Educational institutions such as junior colleges, universities, and technical vocational institutes may provide these prerequisite courses as part of an integrated program in nuclear medicine technology (i.e., two to four years).

E. Operational Policies

Students may not take the responsibility nor the place of qualified staff. However, students may be permitted to perform procedures after demonstrating proficiency, with careful supervision.

F. Continuing Program Evaluation

1. Periodic and systematic review of the program's effectiveness must be documented.

2. One element of program evaluation shall be the initial employment of graduates of the program.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX E—STANDARDS FOR ACCREDITATION OF EDUCATIONAL PROGRAMS FOR RADIATION THERAPY TECHNOLOGISTS

A. Sponsorship

1. Educational programs may be established in:

(a) Community and junior colleges, senior colleges, and universities

(b) Hospitals, clinics, or autonomous radiation oncology centers meeting the criteria for major cancer management centers or meeting demonstrably equivalent standards;

(c) Medical schools; and

(d) Postsecondary vocational/technical schools and institutions.

2. The sponsoring institution and affiliates, if any, must be accredited by recognized agencies or meet equivalent standards. When more than one clinical education center is used, each must meet the standards of a major cancer management center.

3. When didactic preparation and supervised clinical education are not provided in the same institution, accreditation must be obtained by the sponsoring institution for the total program. This institution will be the one responsible for admission, curriculum, and academic credit. The accredited institution shall be responsible for coordinating the program and assuring that the activities assigned to the student in the clinical setting are educational. There shall be a uniform, written, affiliation agreement between the accredited institution and each clinical education center, clearly defining the responsibilities and obligations of each.

B. Curriculum

Educational programs of 24 months and 12 months or their equivalents may be developed. A 24-month program shall admit those candidates with a high school diploma (or equivalent) as outlined in D.1. The 12-month program shall be designed for those students admitted with backgrounds as outlined in D.2.

Instruction must follow a plan which documents:

1. A structured curriculum with clearly written course syllabi which describe competencies and learning objectives to be achieved. The curriculum shall include but not necessarily be limited to the following:

(a) Orientation to radiation therapy technology;
(b) Medical ethics and law;
(c) Methods of patient care;
(d) Medical terminology;
(e) Human structure and function;
(f) Oncologic pathology;
(g) Radiation oncology;
(h) Radiobiology;
(i) Mathematics;
(j) Radiation physics;
(k) Radiation protection;
(l) Radiation oncology technique;
(m) Radiographic imaging; and
(n) Clinical dosimetry.

The curriculum must include a plan for well-structured competency-based clinical education.

2. Assignment of appropriate instructional materials.

3. Classroom presentations, discussions, and demonstrations.

4. Supervised clinical education and laboratory practicum.

5. Evaluation of students to assess knowledge, problem-solving skills, and motor and clinical competencies.

6. Program graduates must demonstrate competencies including, but not limited to, the following:

(a) Practice oral and written communications;
(b) Maintain records of treatment administered;
(c) Perform basic mathematical functions;
(d) Demonstrate knowledge of human structure, function, and pathology;
(e) Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;
(f) Provide basic patient care and cardiopulmonary resuscitation;
(g) Deliver a planned course of radiation therapy;
(h) Verify physician's prescribed course of radiation therapy and recognize errors in computation;
(i) Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;
(j) Produces and utilize immobilization and beam directional devices;
(k) Prepare commonly used brachytherapy sources;
(l) Demonstrate knowledge of methods of calibration of equipment, and quality assurance;
(m) Prepare isodose summations;
(n) Detect malfunctioning equipment;
(o) Apply rules and regulations for radiation safety, and detect defects which might pose a radiation hazard;
(p) Understand the function of equipment and accessories;
(q) Demonstrate knowledge of methods of continuing patient evaluation (follow up);
(r) Apply wedge and compensating filters;
(s) Recognize patients' clinical progress, complications, and demonstrate knowledge of when to withhold treatment until consultation with the physician; and
(t) Interact with patients and families concerning the physical and psychological needs of patients.

C. Resources

1. *Program Officials.* The program must have a qualified program official or officials. Primary responsibilities shall include program development, organization, administration, evaluation, and revision. A program director is necessary; other program officials may be required.

(a) *Program Director*—(1) *Responsibilities.*

—The director of the educational program shall be responsible for the organization, administration, periodic review, continued development, and general effectiveness of the program. The program director's responsibilities in teaching, administration, and coordination of the educational program in radiation therapy technology shall not be adversely affected by educationally unrelated functions.
—In a college-sponsored program, or a hospital-sponsored multiple affiliate program, the program director shall be a employee of the sponsoring institution. A schedule of regular affiliate visits must be maintained.

(2) *Qualifications.*

—Must be a technologist qualified in radiation therapy technology and educational methodologies.
—Must be credentialed in radiation therapy technology or possess suitable equivalent qualifications.
—Must have at least two years' experience as an instructor in an accredited educational program.

(b) *Clinical Supervisor.* Each clinical education center shall appoint a clinical supervisor.

(1) *Responsibilities.* The clinical supervisor shall be responsible for the clinical education and evaluation of students assigned to that clinical education center.

(2) *Qualifications.* Must be a technologist, with suitable experience, qualified in radiation therapy technology and educational methodologies and must be credentialed in radiation therapy technology.

(c) *Medical Director/Medical Advisor*—

(1) *Responsibilities.* The medical director/medical advisor shall work in consultation with the program director in developing the goals and objectives of the program and implementing the standards for achievement.

(2) *Qualifications.* The medical director/medical advisor shall be a qualified radiation oncologist certified by the American

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Board of Radiology, or shall possess suitable equivalent qualifications.

2. *Instructional Staff*— (a) *Responsibilities.* The instructional staff shall be responsible for submitting course outlines for each course assigned by the program director; evaluating students and reporting progress as required by the sponsoring institution; and cooperating with the program director in the periodic review and upgrading of course material.

(b) *Qualifications.* The instructors must be individually qualified, must be effective in teaching the subjects assigned, and must meet the standards required by the sponsoring institution.

(c) *Instructor-to-Student Ratio.* The instructor-to-student ratio shall be adequate to achieve the stated objectives of the curriculum.

(d) *Professional Development.* Programs shall have a policy that encourages continuing education in radiation therapy technology and assures ongoing instruction for the faculty in curriculm design and teaching strategies.

3. *Financial Resources.* Financial resources for continued operation of the educational program must be assured.

4. *Physical Resources*—(a) *General.* Adequate classrooms, laboratories, and other facilities shall be provided. All affiliated institutions shall provide space required for these facilities.

(b) *Equipment and Supplies.* Appropriate modern equipment and supplies in sufficient quantities shall be provided.

(c) *Laboratory.* Energized laboratories must meet Federal and/or State radiation and safety regulations.

(d) *Reference Materials.* An adequate supply of up-to-date books, periodicals, and other reference materials related to the curriculum and the profession shall be readily available to students.

(e) *Records.* Records shall be maintained as dictated by good educational practices.

5. *Instructional Resources.* Instructional aids such as clinical materials, reference materials, and demonstration and other multimedia materials must be provided.

D. Students

Admission

1. Applicants must be high school graduates (or equivalent) with an educational background in basic science and mathematics.

2. For admission to a 12-month program, the candidate must satisfy one of the following requirements:

(a) Graduation from an accredited or equivalent program in radiography.

(b) Successful completion or challenge of courses in the following prerequisite content areas:

—Radiation physics;
—Human structure and function;
—Radiation protection;
—Medical ethics and law;
—Methods of patient care;
—Medical terminology; and
—Mathematics.

(c) Successful demonstration of the following competencies:

—Practice oral and written communications;
—Perform basic mathematical functions;
—Demonstrate knowledge of human structure and function;
—Demonstrate knowledge of radiation physics in radiation interactions and radiation protection techniques;
—Provide basic patient care and cardiopulmonary resuscitation;
—Demonstrate awareness of patterns of physical and emotional stress exhibited by patients;
—Apply rules and regulations for radiation safety, detect defects which might pose a radiation hazard, and maintain control, if a radiation accident occurs; and
—Interact with patients and families concerning patients physical and psychological needs.

E. Continuing Program Evaluation

1. A process for periodic and systematic review of the program's effectiveness must be documented and reflected in policies.

2. Program evaluation shall include the employment performance of recent graduates.

NOTE: Educational programs accredited by an organization recognized by the United States Department of Education are considered to have met these standards.

APPENDIX F—STANDARDS FOR LICENSING RADIOGRAPHERS, NUCLEAR MEDICINE TECHNOLOGISTS, AND RADIATION THERAPY TECHNOLOGISTS

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

A. Licensure

1. Only eligible applicants who have passed the licensure examination shall be licensed as Radiographers, Nuclear Medicine Technologists, or Radiation Therapy Technologists.

2. Licenses shall be renewed at periodic intervals.

B. Eligibility

1. For regular eligibility to take the licensure examination, applicants shall have successfully completed an accredited program of formal education in radiography, nuclear medicine technology, or radiation therapy technology.

2. Special eligibility to take the licensure examination shall be provided for applicants whose training and/or experience are equal to, or in excess of, those of a graduate of an accredited educational program.

C. Examination

A criterion-referenced examination in radiography, nuclear medicine technology, or radiation therapy technology shall be utilized to test the knowledge and competencies of applicants.

D. Continuing Competency

The licensed Radiographer, Nuclear Medicine Technologist, or Radiation Therapy Technologist shall maintain continuing competency in the area in which he/she is practicing.

E. Policies and Procedures

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organization to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.

Appendix G—Standards for Licensing Dental Hygienists and Dental Assistants in Dental Radiography

The following section describes basic elements to be incorporated in credentialing programs of States that choose to regulate personnel who perform radiologic procedures.

Currently, Dental Hygienists are credentialed through individual State licensure processes, all of which include assessment of competence in dental radiography. In all States, Dental Hygienists are required to be licensed prior to practicing. The existing State dental hygiene licensure processes meet the intent and purpose of the Consumer-Patient Radiation Health and Safety Act of 1981 and the standards for licensing Dental Hygienists in dental radiography set forth below.

A. Licensure/Permit

1. To those who have passed a licensure or designated dental radiography examination, a license or permit shall be issued by the State entity responsible for credentialing dental personnel.

2. Licenses or permits shall be renewed at periodic intervals.

B. Eligibility

1. An individual shall provide proof of graduating student status or graduation from an accredited or approved dental hygiene or dental assisting education program.

2. For dental assistants, special eligibility to take the examination shall be provided to applicants with appropriate combinations of training and/or experience.

C. Examination

A criterion-referenced examination in dental radiography shall be utilized to test the knowledge and competencies of applicants.

D. Continuing Competency

The Dental Hygienist or Dental Assistant shall be required to maintain continuing competency in the area in which he/she is practicing.

E. Policies and Procedures

An organization that seeks to be recognized for the certifying of personnel shall adopt definite policies to ensure validity, objectivity, and fairness in the certifying process. The National Commission for Health Certifying Agencies (NCHCA) has published suitable criteria for a certifying organization to adopt with respect to policies for: (1) Determination of appropriate examination content (but not the actual content for any specific occupation); (2) construction of examinations; (3) administration of examinations; and (4) fulfilling responsibilities to applicants. An organization (whether an NCHCA member or not) that adopts these or equivalent criteria will meet all of the requirements of this section of these standards.

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SUBCHAPTER G—OCCUPATIONAL SAFETY AND HEALTH RESEARCH AND RELATED ACTIVITIES

PART 80—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subparts A–C [Reserved]

Subpart D—Tuition Fees for Direct Training

Sec.
80.41 Applicability.
80.42 Definitions.
80.43 Tuition fees.
80.44 Schedule of fees.
80.45 Procedure for payment.
80.46 Refunds.

AUTHORITY: Sec. 501, 65 Stat. 290; 31 U.S.C. 483a.

SOURCE: 38 FR 16645, June 25, 1973, unless otherwise noted.

Subparts A–C [Reserved]

Subpart D—Tuition Fees for Direct Training

§ 80.41 Applicability.

The provisions of this subpart set forth the policies of the National Institute for Occupational Safety and Health with respect to its charging fees for direct training in occupational safety or health.

§ 80.42 Definitions.

Any term not defined herein shall have the same meaning as given it in the act. As used in this subpart:

(a) "Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.).

(b) "Direct training" means all technical training courses conducted directly by NIOSH for personnel of State and local governmental agencies, other Federal agencies, private industries, universities, and other non-NIOSH agencies and organizations.

(c) "NIOSH" or "Institute" means the National Institute for Occupational Safety and Health.

(d) "Registration Office" means the Direct Training Registration Office, NIOSH, 1014 Broadway, Cincinnati, Ohio 45202.

§ 80.43 Tuition fees.

In accordance with the provisions of the subpart, the National Institute for Occupational Safety and Health will charge fees for all students attending NIOSH direct training courses which commence on or after July 1, 1973.

§ 80.44 Schedule of fees.

(a) Tuition fees will be computed on the basis of the cost to the Government for the Institute's participation in the course, as determined by the Director of the Institute.

(b) Total tuition charges for each course will be set forth in the course announcement.

§ 80.45 Procedure for payment.

(a) Applications for direct training courses shall be completed and submitted to the registration office in accordance with the instructions issued by that office.

(b) Federal agency personnel shall, upon notification of their acceptance, submit a letter identifying the agency and office to be billed, the agency order number, and any code numbers or other information necessary for billing purposes.

(c) All other applicants shall, upon notification of their acceptance by NIOSH, submit a check payable to the National Institute for Occupational Safety and Health in the amount indicated by the course announcement prior to the commencement of the training course.

§ 80.46 Refunds.

An applicant may withdraw his application and receive full reimbursement of the fee provided that written notification to the registration office is mailed no later than 10 days before the commencement of the course for which registration has been submitted.

PART 85—REQUESTS FOR HEALTH HAZARD EVALUATIONS

Sec.

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AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and sec. 508, 83 Stat. 803; 30 U.S.C. 957.

SOURCE: 37 FR 23640, Nov. 7, 1972, unless otherwise noted.

§ 85.1 Applicability.

This Part 85 applies to health hazard evaluations requested by any employer or authorized representative of employees under section 20(a)(6) of the Occupational Safety and Health Act of 1970 or section 501(a)(11) of the Federal Mine Safety and Health Act of 1977. This part is not intended to preclude the use of other channels of communication with the National Institute for Occupational Safety and Health to obtain information and technical assistance concerning toxic substances or physical agents.

[45 FR 2652, Jan. 14, 1980]

§ 85.2 Definitions.

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the respective Acts. As used in this part:

"OSH Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651, et seq.).

"FMSH Act" means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801, et seq.).

"Authorized representative of employees" means any person or organization meeting the conditions specified in § 85.3-1(e) (1), (2), or (3).

"Employee" has the same meaning as stated in the OSH Act and for the purposes of this part includes "miner" as defined in the FMSH Act.

"Employer" has the same meaning as stated in the OSH Act and for the purposes of this part includes "Operator" as defined in the FMSH Act.

"Health hazard evaluation" means the investigation and the determination of potentially toxic or hazardous effects of: (a) any substance normally used or found in any place of employment to which the OSH Act is applicable, or (b) any substance or physical agent normally used or found in any place of employment to which the FMSH Act is applicable.

"Investigation" means a physical inspection of the place of employment under section 8 of the OSH Act or section 103 of the FMSH Act and includes inspection, sampling, observations, review of pertinent records, and other measurements reasonably necessary to determine whether any substance or physical agent found in the place of employment has potentially toxic or hazardous effects in the concentrations or levels used or found.

"NIOSH" means the National Institute for Occupational Safety and Health, Center for Disease Control, Public Health Service, Department of Health and Human Services.

"NIOSH officer" means a NIOSH employee who has been authorized by the Director, NIOSH, to conduct investigations according to this part.

"Physical agent" means any condition produced by the environment and/or work processes that can result in hazardous effects as defined in this section. Examples of physical agents are noise, temperature, illumination, vibration, radiation, and pressure.

"Place of employment" means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace, or environment where work is performed by any employee of an employer.

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"Substance" means any chemical or biological agent or dust which has the potential to produce toxic effects.

"Toxic effects" or "hazardous effects" are those effects which result in short- or long-term disease, bodily injury, affect health adversely, or endanger human life.

[45 FR 2652, Jan. 14, 1980]

§ 85.3 Procedures for requesting health hazard evaluations.

(a) Requests for health hazard evaluations should be addressed to the National Institute for Occupational Safety and Health as follows:

(1) *Requests from general industry.* Hazard Evaluations and Technical Assistance Branch, Division of Surveillance, Hazard Evaluations, and Field Studies, NIOSH, 4676 Columbia Parkway, Cincinnati, OH 45226.

(2) *Requests from mining industry.* Environmental Investigations Branch, Division of Respiratory Disease Studies, NIOSH, 944 Chestnut Ridge Road, Morgantown, WV 26505.

(b) Requests for health hazard evaluations shall be submitted in writing and signed by either: (1) The employer in whose place of employment the substance or physical agent is normally found, or (2) an authorized representative of employees (see § 85.3–1(e)) in the place of employment where the substance or physical agent is normally found.

[45 FR 2653, Jan. 14, 1980]

§ 85.3–1 Contents of a request for health hazard evaluation.

Each request for health hazard evaluation shall contain:

(a) The requester's name, address, and telephone number, if any.

(b) The name and address of the place of employment where the substance or physical agent is normally found.

(c) The specific process or type of work which is the source of the substance or physical agent, or in which the substance or physical agent is used.

(d) Details of the conditions or circumstances which prompted the request.

(e) A statement, if the requester is not the employer, that the requester is:

(1) An authorized representative or an officer of the organization representing the employees for purposes of collective bargaining; or

(2) An employee of the employer and is authorized by two or more employees employed in the same place of employment to represent them for purposes of these Acts (each such authorization shall be in writing and a copy submitted with the request for health hazard evaluation); or

(3) One of three or less employees employed in the place of employment where the substance or physical agent is normally found.

(f) A statement indicating whether or not the name(s) of the requester or those persons who have authorized the requester to represent them may be revealed to the employer by NIOSH.

(g) The following supplementary information if known to the requester:

(1) Identity of each substance or physical agent involved;

(2) The trade name, chemical name, and manufacturer of each substance involved;

(3) Whether the substance or its container or the source of the physical agent has a warning label; and

(4) The physical form of the substance or physical agent, number of people exposed, length of exposure (hours per day), and occupations of exposed employees.

NOTE: NIOSH has developed two forms entitled "Request for Health Hazard Evaluation" and "Request for Mining Health Hazard Evaluation" to assist persons in requesting evaluations. The forms are available upon request from the offices listed in § 85.3(a) (1) and (2) or from the Regional Consultant for Occupational Safety and Health in any Regional Office of the Department of Health and Human Services.

[45 FR 2653, Jan. 14, 1980]

§ 85.4 Acting on requests.

(a) Upon receipt of a request for health hazard evaluation submitted under this part, NIOSH will determine whether or not there is reasonable cause to justify conducting an investigation.

(b) If NIOSH determines that an investigation is justified, a NIOSH officer will inspect the place of employment, collect samples where appropriate, and perform tests necessary to the conduct of a health hazard evaluation, including medical examinations of employees.

(c) If NIOSH determines that an investigation is not justified, the requester will be notified in writing of the decision.

[45 FR 2653, Jan. 14, 1980]

§ 85.5 Authority for investigations.

(a) NIOSH officers who have been issued official NIOSH credentials (Form No. CDC/NIOSH 2.93) are authorized by the Director, NIOSH, under sections 20(a) (6) and 8 of the OSH Act and sections 501(a)(11) and 103 of the FMSH Act: To enter without delay any place of employment for the purpose of conducting investigations of all pertinent processes, conditions, structures, machines, apparatus, devices, equipment, records, and materials within the place of employment; and to conduct medical examinations, anthropometric measurements, and functional tests of employees within the place of employment as may be directly related to the specific health hazard evaluation being conducted. Investigations will be conducted in a reasonable manner, during regular working hours or at other reasonable times and within reasonable limits. In connection with any investigation, the NIOSH officers may question privately any employer, owner, operator, agent, or employee from the place of employment; and review, abstract, and duplicate records required by the Acts and regulations and any other related records.

(b) Areas under investigation which contain information classified by any agency of the United States Government in the interest of national security will be investigated only by NIOSH officers who have obtained the proper security clearance and authorization.

[45 FR 2653, Jan. 14, 1980]

§ 85.6 Advance notice of visits.

(a) Advance notice of visits to the place of employment may be given to expedite a thorough and effective investigation. Advance notice will not be given when, in the judgment of the NIOSH officer, giving such notice would adversely affect the validity and effectiveness of the investigation.

(b) Where a request in accordance with this part has been made by an authorized representative of employees, advance notice in accordance with paragraph (a) of this section will be given by NIOSH to the requester, the representative of the employees for purposes of collective bargaining if such representative is other than the requester, and to the employer.

(c) Where a request in accordance with this part has been made by any employer, advance notice will be given by NIOSH to the employer. Upon the request of the employer, NIOSH will inform the authorized representative of employees of the visit: *Provided,* The employer furnishes NIOSH in writing with the identity of such representative and with such information as is necessary to enable NIOSH promptly to inform such representative of the visit.

§ 85.7 Conduct of investigations.

(a) Prior to beginning an investigation, NIOSH officers shall present their credentials to the owner, operator, or agent in charge at the place of employment, explain the nature, purpose, and scope of the investigation and the records specified in § 85.5 which they wish to review. Where the investigation is the result of a request submitted by an authorized representative of employees, a copy of the request shall be provided to the employer, except where the requester or any person authorizing the requester pursuant to § 85.3-1(e)(2) has indicated that NIOSH not reveal his name to the employer, in which case a summary of the basis for the request shall be provided to the employer.

(b) At the commencement of an investigation, the employer should precisely identify information which can be obtained in the workplace or workplaces to be inspected as trade secrets. If the NIOSH officer has no clear reason to question such identification, such information shall not be dis-

closed except in accordance with the provisions of section 20(a)(6) and section 15 of the OSH Act or section 501(a)(11) of the FMSH Act. However, if NIOSH at any time questions such identification by an employer, not less than 15 days' notice to an employer shall be given of the intention to remove the trade secret designation from such information. The employer may within that period submit a request to the Director, NIOSH, to reconsider this intention and may provide additional information in support of the trade secret designation. The Director, NIOSH, shall notify the employer in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

(c) NIOSH officers are authorized to collect environmental samples and samples of substances or measurements of physical agents (including measurement of employee exposure by the attachment of personal sampling devices to employees with their consent), to take or obtain photographs related to the purpose of the investigation, employ other reasonable investigative techniques, including medical examinations of employees with the consent of such employees, and to question privately any employer, owner, operator, agent, or employee. The employer shall have the opportunity to review photographs taken or obtained for the purpose of identifying those which contain or might reveal a trade secret.

(d) NIOSH officers shall comply with all safety and health rules and practices at the place of employment being investigated, and they shall provide and use appropriate protective clothing and equipment. In situations requiring specialized or unique types of protective equipment, such equipment shall be furnished by the employer.

(e) The conduct of investigations shall be such as to preclude unreasonable disruption of the operations of the employer's establishment.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980; 49 FR 4739, Feb. 8, 1984]

§ 85.8 Provision of suitable space for employee interviews and examinations; identification of employees.

An employer shall, in request of the NIOSH officer, provide suitable space, if such space is reasonably available, to NIOSH to conduct private interviews with, and examinations of, employees. NIOSH officers shall consult with the employer as to the time and place of the medical examination and shall schedule such examinations so as to avoid undue disruption of the operations of the employer's establishment. NIOSH shall conduct, and assume the medical costs of, examinations conducted under this part.

§ 85.9 Representatives of employers and employees; employee requests.

(a) NIOSH officers shall be in charge of investigations. Where the request for a health hazard evaluation has been made by an authorized representative of employees, a representative of the employer and a representative authorized by his employees who is an employee of the employer shall be given an opportunity to accompany the NIOSH officer during the initial physical inspection of any workplace for the purpose of aiding the investigation by identifying the suspected hazard. The NIOSH officer may permit additional employer representatives and such additional representatives authorized by employees to accompany him where he determines that such additional representatives will further aid the investigation. However, if in the judgment of the NIOSH officer, good cause has been shown why accompaniment by a third party who is not an employee of the employer is reasonably necessary to the conduct of an effective and thorough investigation of the workplace, such third party may accompany the NIOSH officer during the inspection: *Provided, however,* That access by such persons to areas described in paragraph (d) of this section shall be in accordance with the requirements of such provision, and access to areas described in paragraph (e) of this section shall be with the consent of the employer. A different employer and employee representative may accom-

pany the officer during each different phase of an inspection if this will not interfere with the conduct of the investigation.

(b) NIOSH officers are authorized to resolve all disputes as to who is the representative authorized by the employer and employees for the purpose of this section. If there is no authorized representative of employees, or if the NIOSH officer is unable to determine with reasonable certainty who is such representative, he shall consult with a reasonable number of employees concerning matters directly related to the health hazard evaluation.

(c) NIOSH officers are authorized to deny the right of accompaniment under this section to any person whose conduct interferes with a fair and orderly physical inspection.

(d) With regard to information classified by an agency of the U.S. Government in the interest of national security, only persons authorized to have access to such information may accompany an officer in areas containing such information.

(e) Upon request of an employer, any representative authorized under this § 85.9 by employees in any area containing trade secrets shall be an employee in that area or an employee authorized by the employer to enter that area.

§ 85.10 Imminent dangers.

Whenever, during the course of, or as a result of, an investigation under this part, the NIOSH officer believes that there is a reasonable basis for an allegation of an imminent danger, NIOSH will immediately advise the employer and those employees who appear to be in immediate danger of such allegation and will inform appropriate representatives of the Department of Labor or the State agency designated under section 18(b) of the OSH Act.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

§ 85.11 Notification of determination to employers, affected employees and Department of Labor.

(a) Upon conclusion of an investigation, NIOSH will make a determination concerning the potentially toxic or hazardous effects of each substance or physical agent investigated as a result of the request for health hazard evaluation. At a minimum, the determination will: (1) Identify each substance or physical agent involved and describe, where appropriate, the concentrations or levels of the substance or physical agent found in the place of employment and the conditions of use, and (2) state whether each substance or physical agent has potentially toxic or hazardous effects in the concentrations or levels found, as well as the basis for the judgments.

(b) Copies of the determination will be mailed to the employer and to the authorized representatives of employees.

(c) Except as hereinafter provided, the employer shall post a copy of the determination for a period of 30 calendar days at or near the workplace(s) of affected employees. The employer shall take steps to insure that the posted determinations are not altered, defaced, or covered by other material during such period. The employer will not be required to post the determination if the employer requests that copies of the determination be mailed to affected employees and furnishes NIOSH with a list of the names and mailing addresses of the employees employed in the workplace(s) designated by the NIOSH Officer. In the latter event, NIOSH will mail such copies to affected employees at the mailing addresses provided by the employer.

(d) For purposes of this section, the term "affected employees" means those employees determined by NIOSH to be exposed to the substance(s) or physical agent(s) which is the subject of the health hazard evaluation.

(e) Copies of determinations made under the OSH Act will be forwarded to the Department of Labor and the appropriate State agency designated under section 18(b) of the OSH Act. Copies of determinations made under the FMSH Act will be forwarded to the Mine Safety and Health Administration of the Department of Labor; the Bureau of Mines, Department of the Interior; and the State agency which, in the judgment of NIOSH,

would benefit the most from the information. If NIOSH determines that any substance or physical agent has potentially toxic or hazardous effects at the concentrations or levels at which it is used or found in a place of employment, and the substance or physical agent is not covered by a safety or health standard established under section 6 of the OSH Act or section 101 of the FMSH Act, NIOSH will immediately submit the determination to the Secretary of Labor, together with all pertinent criteria.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

§ 85.12 Subsequent requests for health hazard evaluations.

If a request is received for a health hazard evaluation in a place of employment in which an evaluation under this part was made previously, NIOSH may make another investigation if, as a result of the passage of time or additional information, another investigation would be consistent with the purposes of the Acts.

[45 FR 2654, Jan. 14, 1980]

PART 85a—OCCUPATIONAL SAFETY AND HEALTH INVESTIGATIONS OF PLACES OF EMPLOYMENT

Sec.

85a.1 Applicability.
85a.2 Definitions.
85a.3 Authority for investigations of places of employment.
85a.4 Procedures for initiating investigations of places of employment.
85a.5 Conduct of investigations of places of employment.
85a.6 Provision of suitable space for employee interviews and examinations.
85a.7 Imminent dangers.
85a.8 Reporting of results of investigations of places of employment.

AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and sec. 508, 83 Stat. 803; 30 U.S.C. 957.

SOURCE: 41 FR 45002, Oct. 14, 1976, unless otherwise noted.

§ 85a.1 Applicability.

(a) Except as otherwise provided in paragraph (b) of this section, the provisions of this part apply to investigations of places of employment which are conducted by NIOSH under sections 20 and 8 of the Occupational Safety and Health Act of 1970 and sections 501 and 103 of the Federal Mine Safety and Health Act of 1977.

(b) The provisions of this part do not apply to those activities covered by Part 85 of this chapter.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.2 Definitions.

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the Acts. As used in this part:

(a) "OSH Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.) and "FMSH Act" means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.).

(b) "Assistant Regional Director" means any one of the ten Occupational Safety and Health Administration Assistant Regional Directors for Occupational Safety and Health.

(c) "Informed consent" means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonably to be expected;

(3) A description of any benefits reasonably to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the person is free to withdraw his consent and to discontinue participation in the investigation any time without prejudice to the subject.

(d) "Investigation" means research projects, experiments, demonstrations, studies, and similar activities of NIOSH which are conducted under section 20 of the OSH Act and section 501 of the FMSH Act.

(e) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

(f) "NIOSH" means the National Institute for Occupational Safety and Health of the Center for Disease Control, Public Health Service, Department of Health and Human Services.

(g) "NIOSH authorized representative" means a person authorized by NIOSH to conduct investigations of places of employment, including any person that is fulfilling a contract agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act.

(h) "NIOSH Regional Office" means any one of the ten Department of Health and Human Services Regional Offices, the addresses of which are specified in § 5.31 of Title 45, Code of Federal Regulations.

(i) "Place of employment" means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by any employee of an employer.

(j) "MSHA District Office" means any one of the Mine Safety and Health Administration's District Offices.

(k) "BOM" means the Bureau of Mines, Department of the Interior.

(l) "Employee" has the same meaning as stated in the OSH Act and for the purposes of this part includes "miner" as defined in the FMSH Act.

(m) "Employer" has the same meaning as stated in the OSH Act and for the purposes of this part includes "operator" as defined in the FMSH ACT.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.3 Authority for investigations of places of employment.

(a) NIOSH authorized representatives who have been issued official NIOSH credentials are authorized by the Director, NIOSH, under sections 20 and 8 of the OSH Act, sections 501 and 103 of the FMSH Act, and this part. To enter without delay any place of employment for the purpose of conducting investigations of all pertinent processes, conditions, structures, machines, apparatus, devices, equipment, and materials within the place of employment; and to conduct medical examinations, anthropometric measurements and functional tests of employees within the place of employment as may be directly related to the specific investigation being conducted. Such investigations will be conducted in a reasonable manner, during regular working hours or at other reasonable times and within reasonable limits. In connection with any investigations, such NIOSH authorized representatives may question privately any employer, owner, operator, agent, or employee from the place of employment; and review, abstract, or duplicate employment records, medical records, records required by the Act and regulations, and other related records. In those instances where systems of records subject to review, abstraction or duplication are of a confidential nature, such as medical records, and are abstracted or duplicated, NIOSH will maintain such systems in accordance with the Privacy Act of 1974 (5 U.S.C. 552a) and the implementing regulation of the Department of Health and Human Services (45 CFR Part 5b).

(b) Areas under investigation which contain information classified by any agency of the United States Government in the interest of national security will be investigated only by NIOSH authorized representatives who have obtained the appropriate security clearance and authorization.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.4 Procedures for initiating investigations of places of employment.

(a) Except as otherwise provided in paragraph (b) of this section, NIOSH authorized representatives will contact an official representative of the place of employment prior to any site visits

and will provide the details of why an investigation of the place of employment is being conducted. Prior to the initiation of a site visit of a place of employment, representatives of the following organizations will be advised of the site visit and the reason for its conduct:

(1) The appropriate State agency designated under section 18(b) of the OSH Act, or if no State agency has been designated under the OSH Act and in the case of the FMSH Act, the State agency which, in the judgment of NIOSH, would benefit the most from the investigation's findings;

(2) If there is a local union at the place of employment, the local president, business manager or other appropriate individual;

(3) The appropriate Assistant Regional Director, when investigations are conducted under the OSH Act;

(4) The appropriate MSHA District Office; the Director, BOM, and the Assistant Director for Mining, BOM, when investigations are conducted under the FMSH Act.

(b) Advance notice of site visits will not be given to the place of employment or local union at the place of employment when, in the judgment of the NIOSH authorized representatives, giving such notice would adversely affect the validity and effectiveness of an investigation. Those individuals and organizations specified in § 85a.4(a)(1), (a)(3) and (a)(4) will be notified prior to the initiation of such a site visit. After the site visit has been initiated, and, as soon as possible thereafter, the NIOSH authorized representatives will contact those individuals specified in § 85a.4(a)(2) concerning the nature and details of the site visit.

(c) In those instances where site visits are not necessary to the conduct of an investigation, the NIOSH authorized representatives will contact an official representative of the place of employment either verbally or through a written communication and provide the details of why an investigation of the place of employment is being conducted. If appropriate, the NIOSH authorized representatives will contact those individuals stipulated in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section about the nature and details of the investigation.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.5 Conduct of investigations of places of employment.

(a)(1) Prior to beginning a site visit, NIOSH authorized representatives will present their credentials to the employer, owner, operator or agent in charge at the place of employment, explain the nature, purpose and scope of the investigation and the records specified in § 85a.3 which they wish to review, abstract or duplicate.

(2) In those instances where site visits are not necessary to the conduct of an investigation and the initial contact is made verbally, NIOSH authorized representatives will, at the request of the employer, owner, operator or agent in charge at the place of employment, provide a written explanation of the nature, purpose and scope of the investigation and the records specified in § 85a.3 which they wish to review, abstract or duplicate.

(b)(1) At the commencement of an investigation, the employer, owner, operator or agent in charge at the place of employment shall precisely identify that information which is trade secret and might be seen or obtained by the NIOSH authorized representatives during the investigation. If the NIOSH authorized representatives have no clear reason to question such identification, such information will not be disclosed by NIOSH in accordance with the provisions of section 15 of the OSH Act. Generally, NIOSH will not question trade secret designations; however, if NIOSH at any time does question such identification, not less than 15 days' notice to the employer, owner, operator or agent will be given of the intention to remove the trade secret designation from such information. The employer, owner, operator or agent may within that period submit a request to the Director, NIOSH, to reconsider this intention and may provide additional information in support of the trade secret designation. The Director, NIOSH, will notify the employer, owner, operator or agent in writing of the decision

which will become effective no sooner than 15 days after the date of such notice.

(2) In those instances where the NIOSH authorized representative is a person fulfilling a contact agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act, the employer, owner, operator or agent in charge at the place of employment may, after advising the NIOSH contractor or consultant in writing, elect to withhold information deemed to be a trade secret from such a NIOSH authorized representative or prohibit entry into the area of the place of employment where such entry will reveal trade secrets. In those instances, where the subject information is needed or access to the area of the place of employment is necessary, in the judgment of NIOSH, to fulfill the goals of the investigation, NIOSH regular employees will then obtain the information or enter the subject area of the place of employment.

(c)(1) NIOSH authorized representatives will be in charge of site visits conducted pursuant to this part.

(2) Where there is a request by the representative of the State agency and/or employees, who were notified pursuant to § 85a.4(a)(1) or § 85a.4(a)(2) to accompany the NIOSH authorized representatives during the site visit of the place of employment, the NIOSH authorized representatives will allow this request if they determine that this will aid the investigation; or where, in the judgment of the NIOSH authorized representatives, good cause has been shown why accompaniment by a third party who is not an employee of the employer is reasonably necessary to the conduct of an effective and thorough site visit, they may permit such third party to accompany them during the site visit: *Provided, however,* That access by such person(s) to areas described in § 85a.5(c)(4) shall be in accordance with the requirements of such provision and access to areas containing trade secrets shall be with the consent of the employer, owner, operator or agent in charge at the place of employment.

(3) NIOSH authorized representatives are authorized to deny the right of accompaniment under this paragraph to any person whose conduct in their judgment interferes with a fair and orderly site visit. In all instances, a representative of the employer shall be permitted to accompany the NIOSH authorized representatives during the site visit of the place of employment.

(4) With regard to information classified by an agency of the United States Government in the interest of national security, only persons authorized to have access to such information may accompany NIOSH authorized representatives in areas containing such information.

(d)(1) NIOSH authorized representatives are authorized: To collect environmental samples and samples of substances; to measure environmental conditions and employee exposures (including measurement of employee exposure by the attachment of personal sampling devices to employees with their consent); to take or obtain photographs, motion pictures or videotapes related to the purpose of the investigation; to employ other reasonable investigative techniques, including medical examinations, anthropometric measurements and standardized and experimental functional tests of employees with the informed consent of such employees; to review, abstract, and duplicate such personnel records as are pertinent to mortality, morbidity, injury, safety, and other similar studies; and to question and interview privately any employer, owner, operator, agency, or employee from the place of employment. The employer, owner, operator, or agency shall have the opportunity to review photographs, motion pictures, and videotapes taken or obtained for the purpose of identifying those which contain or might reveal a trade secret.

(2) Prior to the conduct of medical examinations, anthropometric measurements or functional tests of any employees, the NIOSH authorized representatives will obtain approval of the procedures to be utilized from the NIOSH Human Subjects Review Board and no employee examination, measurement or test will be undertaken without the informed consent of such employee.

(e) NIOSH authorized representatives will comply with all safety and health rules and practices at the place of employment and all NIOSH, Occupational Safety and Health Administration, and Mine Safety and Health Administration regulations and policies during a site visit and will provide and use appropriate protective clothing and equipment. In situations requiring specialized or unique types of protective equipment, such equipment shall be furnished by the employer, owner, operator or agent in charge at the place of employment.

(f) The conduct of site visits will be such as to preclude unreasonable disruption of the operations of the place of employment.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980; 49 FR 4739, Feb. 8, 1984]

§ 85a.6 Provision of suitable space for employee interviews and examinations.

An employer, owner, operator or agent in charge at the place of employment shall, on request of the NIOSH authorized representatives, provide suitable space at the place of employment, if such space is reasonably available, to NIOSH to conduct private interviews with, and medical examinations, anthropometric measurements and functional tests of employees. NIOSH authorized representatives will consult with the employer, owner, operator or agent as to the time and place of the private interviews, medical examination, anthropometric measurements and functional tests and will schedule same so as to avoid undue disruption of work at the place of employment. NIOSH will conduct the medical interviews, measurements, examinations and tests specified under this part at its own expense.

§ 85a.7 Imminent dangers.

Whenever, during the course of, or as a result of, an investigation under this part, the NIOSH authorized representatives believe there is a reasonable basis for an allegation of an imminent danger, NIOSH will immediately advise the employer, owner, operator or agent in charge at the place of employment and those employees who appear to be in immediate danger of such allegation and will inform the agencies identified in § 85a.4(a)(1), (a)(3), and (a)(4).

[41 FR 45002, Oct. 16, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

§ 85a.8 Reporting of results of investigations of places of employment.

(a)(1) Specific reports of investigations of each place of employment under this part, with identification of the place of employment, will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, with copies to the appropriate officials and Agencies notified pursuant to § 85a.4(a). Prior to release of such reports, a preliminary report will be sent by NIOSH to the employer, owner, operator or agent for review for trade secret information and technical inaccuracies that may inadvertently be presented in the report. If requested in writing, the data used to compile the reports will be made available by NIOSH to the employer, owner, operator or agent in charge at the place of employment, except that data will not be released in a form that is individually identifiable.

(2) All specific reports of investigations of each place of employment under this part will be available to the public from the NIOSH Regional Consultant for Occupational Safety and Health in the appropriate NIOSH Regional Office.

(3) In certain instances, specific reports of investigations of each place of employment will not be prepared. In such instances, a closing conference at the place of employment will be conducted by the NIOSH authorized representatives and those individuals participating in the site visit to discuss the findings of the site visit and appropriate recommendations.

(b)(1) Any specific findings of individual employee medical examinations, anthropometric measurements and functional tests will be released by NIOSH authorized representatives to the company physician, private physician, or other person only pursuant to the written authorization of the employee; otherwise, the specific findings and other personal records concerning

individuals will be maintained in accordance with 45 CFR Part 5b and section 3 of the Privacy Act of 1974 (5 U.S.C. 552a). Notice of all NIOSH systems of records as defined in 45 CFR 5b.1(n) as a result of the investigations of places of employment pursuant to this part will be published in the FEDERAL REGISTER under Notices of Systems of Records for the Department of Health and Human Services.

(2) In cases where an employee shows positive significant medical findings, the employee and the physician(s) designated by the employee under § 85a.8(b)(1) will be immediately notified by NIOSH.

(3) A summary of the findings of the examinations for each employee will be sent by NIOSH to the individual.

(c) The findings of a total investigation generally will be disseminated as part of NIOSH criteria documents, NIOSH technical reports, NIOSH information packets, scientific journals, presentations at technical meetings, or in other similar manners. These findings of a total investigation will be presented in a manner which does not identify any specific place of employment; however, it should be noted that the specific reports of investigations of each place of employment under this part are subject to mandatory disclosure, upon request, under the provisions of the Freedom of Information Act (5 U.S.C. 552).

PART 86—GRANTS FOR EDUCATION PROGRAMS IN OCCUPATIONAL SAFETY AND HEALTH

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AUTHORITY: Sec. 8(g), 84 Stat. 1600, 29 U.S.C. 657(g); sec. 21(a), 84 Stat. 1612, 29 U.S.C. 670(a).

SOURCE: 40 FR 29076, July 10, 1975, unless otherwise noted.

Subpart A—General

§ 86.1 Applicability.

The regulations of this part are applicable to the award of training grants and direct traineeships pursuant to section 21(a)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 670(a)(1)) to assist in providing an adequate supply of qualified personnel to carry out the purposes of the Act.

§ 86.2 Definitions.

Any term not defined herein shall have the same meaning as given it in the Act. As used in this part:

(a) "Act" means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.).

(b) [Reserved]

(c) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(d) "State" means a State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands,

American Samoa, Guam, and the Trust Territory of the Pacific Islands.

(e) "Training" means job-specific skill development, the purpose of which is to provide qualified personnel to carry out the purposes of the Act.

[40 FR 29076, July 10, 1975, as amended at 47 FR 53012, Nov. 24, 1982]

§ 86.3 Inventions and discoveries.

Any grant award pursuant to § 86.14 or § 86.33 is subject to the regulations of the Department of Health and Human Services as set forth in 45 CFR Parts 6 and 8, as amended. Such regulations shall apply to any activity for which grant funds are in fact used whether within the scope of the project as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Secretary to assure that no contracts, assignments or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligations. Laboratory notes, related technical data, and information pertaining to inventions and discoveries shall be maintained for such periods, and filed with or otherwise made available to the Secretary, or those he may designate at such times and in such manner, as he may determine necessary to carry out such Department regulations.

§ 86.4 Publications and copyrights.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose, of such materials and to authorize others to do so.

§ 86.5 Grant appeals procedure.

The informal Public Health Service procedure for resolution of post-award grant disputes set forth in Subpart D of Part 50 of this title and the Department post-award grant appeals procedure in 45 CFR Part 16 are applicable to any award made pursuant to this part.

Subpart B—Occupational Safety and Health Training Grants

§ 86.10 Nature and purpose of training grants.

(a) *Long-term training project grant.* A long-term training project grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable activities, hereinafter termed the "project," that are undertaken to establish, strengthen, or expand graduate, undergraduate, or special training, of persons in the field of occupational safety and health. Such grants may be used to support training in, for example, occupational medicine, industrial hygiene, industrial nursing and occupational safety engineering and the training of technicians and paraprofessionals in such areas.

(b) *Short-term training project grant.* A short-term training project grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable activities, hereinafter termed the "project" that are undertaken to provide intensive training programs of less than 1 year for any one or a combination of the following purposes:

(1) To provide specialized instruction for occupational safety and health professional or career personnel which will increase their competence in an area in their respective fields.

(2) To prepare or expand the capabilities of occupational safety and health professional or career personnel for leadership roles as administrators or supervisors, and

(3) To prepare or expand the teaching capabilities of occupational safety and health professionals and career personnel.

(c) *Educational Resource Center Grant.* An educational resource center grant is an award of funds to an eligible institution or agency, hereinafter called the "grantee," to pay part or all of the costs of organized identifiable

ties, hereinafter termed the ect," that are undertaken to pro- or the combination of long-term short-term training activities as ibed in § 86.13 (c).

R 29076, July 10, 1975, as amended at 52401, Sept. 30, 1977]

Eligibility.

Eligible applicants. Any public or te educational or training agency stitution located in a state is eligi- apply for a grant under this sub-

Projects eligible for long-term or -term training grants or educa- l resource center grants. Any ct found by the Secretary to be a term training project within the ing of § 86.10(a) or a short-term ing project within the meaning of 0(b) or an educational resource r grant project within the mean- f § 86.10(c) shall be eligible for a award. However, no applicant is le for assistance for a separate ing project grant in any project d in which it receives an educa- l resource center grant. Nothing e section shall prevent an existing ing grant from being incorporat- to an educational resource center t award.

R 29076, July 10, 1975, as amended at R 52401, Sept. 30, 1977; 47 FR 53012, 24, 1982]

2 Application for a grant.

An application for a grant under subpart shall be submitted to the etary at such time and in such and manner as the Secretary prescribe.[1] The application shall ain a full and adequate descrip- of the project and of the manner hich the applicant intends to con- the project in accordance with requirements of this subpart, and udget and justification of the unt of grant funds requested, and other pertinent information as Secretary may require.

pplications and instructions may be ob- ed from the Procurement and Grants ce, Centers for Disease Control, Atlanta, 30333.

(b) The application shall be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

[40 FR 29076, July 10, 1975, as amended at 49 FR 38117, Sept. 27, 1984]

§ 86.13 Project requirements.

(a) An approvable application for a long-term training grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission.

(1) Provision of a method for development of the training curriculum and any attendant training materials and resources;

(2) Provision of a method for implementation of the needed training;

(3) Provision of an evaluation methodology, including the manner in which such methodology will be employed, to measure the achievement of the objectives of the training program; and

(4) Provision of a method by which trainees will be selected.

(b) In addition to the requirements set forth in paragraph (a) of this section, an approvable application for a short-term training grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission.

(1) Provision of a methodology to assess the particular skills, or knowledge that prospective trainees need to develop;

(2) Provision of at least 18 hours of formal instruction for a period of not less than 2½ days and not more than 1 academic year; and

(3) Assurances that no portion of the Federal funds will be used for (i) in-service training courses designed only for employees of a single agency, institution, or organization; (ii) correspondence courses; (iii) regular courses usually given for academic credit; or (iv) training the grantee's financial officers, program director, or the official who executed the application.

(c) In addition to the requirements set forth in paragraphs (a), (b)(1), and

(b)(3) (ii), (iii) and (iv) of this section, an approvable application for an educational resource center grant must contain each of the following, unless the Secretary determines that the applicant has established good cause for its omission:

(1) A description, supported by appropriate documents, of cooperative arrangements to conduct an educational resource center among a medical school (with an established program in preventive or occupational medicine), a school of nursing, a school of public health or its equivalent, and a school of engineering or its equivalent. Other schools or departments with relevant disciplines and resources—e.g., toxicology, biostatistics, environmental health, law, business administration, education—may be represented and contribute as appropriate to the conduct of the total program.

(2) The identification of an educational resource center Director who possesses a demonstrated capacity for sustained productivity and leadership in occupational safety and health training who shall oversee the general operation of the educational resource center program and shall, to the extent possible, directly participate in training activities.

(3) A description of the full-time professional staff representing various disciplines and qualifications relevant to occupational safety and health and capable of planning, establishing, and carrying out or administering training projects undertaken by the educational resource center.

(4) A description of the training and research expertise, appropriate facilities and ongoing training and research activities in occupational safety and health areas.

(5) A description of its program for conducting education and training of occupational health physicians, occupational health nurses, industrial hygienists/engineers and safety personnel. There shall be full-time students in each of these core disciplines, with a goal of a minimum total of 30 full-time students. Training may also be conducted in other occupational safety and health career categories, e.g., industrial toxicology, biostatistics, epidemiology, and ergonomics. Training programs shall include appropriate field experience including experience with public health and safety agencies and labor-management health and safety activities.

(6) A specific plan for making an impact on the curriculum taught by relevant medical specialties, including radiology, orthopedics, dermatology, internal medicine, neurology, perinatal medicine, and pathology.

(7) A description of its program to assist other institutions or agencies located within the applicant's region including schools of medicine, nursing and engineering, among others, by providing curriculum materials and consultation for curriculum/course development in occupational safety and health, and by providing training opportunities for faculty members.

(8) A specific plan for preparing, distributing, and conducting courses, seminars and workshops to provide short-term and continuing education training courses for physicians, nurses, industrial hygienists, safety engineers and other occupational safety and health professionals, paraprofessionals and technicians, including personnel of labor-management health and safety committees, in the geographical region in which the educational resource center is located. The content and orientation of the curriculum/courses shall take into consideration and address problems relevant to the geographic region served. The goal shall be that the training be made available each year to a minimum of 200-250 trainees representing all of the above categories of personnel with priority given to providing occupational safety and health training to physicians in family practice, as well as in industrial practice, and industrial nurses. These courses shall be structured so that educational institutions, public health and safety agencies, professional societies or other appropriate agencies can utilize them to provide training at the local level to occupational safety and health personnel working in the workplace. Further, the educational resource center shall have a specific plan and demonstrated capability for implementing such training directly and through other in-

itutions or agencies in the region including cooperative efforts with labor nions and industry trade associations here appropriate.

40 FR 29076, July 10, 1975, as amended at 42 FR 52401, Sept. 30, 1977]

86.14 Evaluation and grant award.

Within the limits of funds available or such purpose the Secretary may ward grants to assist in the establishment and operation of those projects which will in his judgment best promote the purposes of section 21(a)(1) of the Act, taking into account:

(a) In the case of long-term training grants:

(1) The need for training in the area or areas of study outlined in the application;

(2) The degree to which the proposal represents a strengthening or expansion of the applicant's program in such areas;

(3) The record of the applicant's effectiveness in training in these or related areas as indicated, among other things, by the placement of its graduates;

(4) The competence of the project staff in relation to the service to be provided;

(5) The reasonableness of the budget in relation to the proposed project;

(6) The applicant's resources, including equipment, facilities, and funds, available for the project;

(7) The current and potential availability of students in the area of study to be offered and their prospective employability as a result of the proposed training;

(8) The extent to which the applicant expects to absorb faculty positions initiated as a result of the grant; and

(9) The degree to which the project adequately provides for the requirements set forth in § 86.13(a).

(b) In the case of short-term training:

(1) The relationship of the contents of the course to the current and emergency training needs to carry out the purposes of the Act;

(2) The qualifications of the instructional staff;

(3) The speed with which the training can be put to use by the persons proposed to be trained;

(4) The reasonableness of the budget in relation to the proposed project;

(5) The success of previous offerings of this course, or related courses;

(6) Evidence of ability to recruit trainees and the estimated number to be enrolled during each course offering; and

(7) The degree to which the proposed project adequately provides for the requirements set forth in § 86.13(b).

(c) In the case of educational resource center grants:

(1) The criteria set forth in paragraphs (a) and (b) of this section.

(2) The degree to which the proposed project adequately provides for the requirements set forth in § 86.13(c).

(d) The amount of any award shall be determined by the Secretary on the basis of his estimate of the sum necessary for all or a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either (1) on the basis of his estimate of the actual indirect costs reasonably related to the project, or (2) on the basis of a percentage, not to exceed 8 percent, of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as travel or supply costs) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary.

(e) All grant awards shall be in writing, shall set forth the amount of funds granted and the period for which support is recommended.

(f) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award

with respect to any approved project or portion thereof. For continuation support, grantees must make separate application annually at such times and in such form as the Secretary may direct.

[40 FR 29076, July 10, 1975, as amended at 42 FR 52402, Sept. 30, 1977]

§ 86.15 Payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses incurred or to be incurred in the performance of the project to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§ 86.16 Use of project funds.

(a) Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project shall be expended solely for carrying out the approved project in accordance with section 21(a) of the Act, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

(b) Prior written approval by the Secretary of revision of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities, which in the case of short term training grants, includes any change in the course dates or training sites.

(c) Grant funds are available for trainee stipends and for tuition, including fees and instructional materials, for travel costs related to training allowances. Stipends and allowances may not be increased or be paid beyond the term of the stipend on account of vacation an individual might have been entitled to but did not take.

(d) Stipends may only be paid to a trainee who is a citizen of the United States, an alien lawfully admitted to the United States for permanent residence, or a permanent resident of Guam, American Samoa, or the Trust Territory of the Pacific Islands.

(e) In the case of short term training grants, stipends may not be paid to persons receiving lecture fees, salary, travel expenses, or payment in any form as members of the course instructional staff.

(f) Grant funds used for alterations and renovations shall be subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, as amended, and with the applicable regulations prescribed pursuant thereto.

§ 86.17 Nondiscrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to, discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which applies to grants made under this subpart, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR Part 80).

(b) Attention is called to the requirements of Title IX of the Education Amendments of 1972 (86 Stat. 373, 20 U.S.C. 1681 et seq.) and in particular to section 901 of such Act which provides that no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance.

(c) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§ 86.18 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Sec-

retary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the governments of the political sudivisions of the State. All grantees other than a State, as defined in this section, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section; and

(ii) Any credits for earned interest pursuant to paragraph (b) of this section; and

(iii) Any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74.

Such total sum shall constitute a debt owed by the grantee to the Federal Government and shall be recovered from the grantee or its successors or assignees by setoff or other action as provided by law.

§ 86.19 Human subjects; animal welfare.

No grant award may be made under this subpart unless the applicant has complied with:

(a) 45 CFR Part 46 pertaining to the protection of human subjects; and

(b) Chapter 1-43 of the Department Grants Administration Manual[2] concerning animal welfare.

§ 86.20 Additional conditions.

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

§ 86.21 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to States and local governments as those terms are defined in Subpart A of that Part 74. The relevant provisions of the following subparts of Part 74 shall also apply to grants to all grantee organizations under this part:

45 CFR PART 74

Subpart	and Subject
A	General.
B	Cash depositories.
C	Bonding and insurance.
D	Retention and custodial requirements for records.
F	Grant-related income.
G	Matching and cost sharing.
K	Grant payment requirements.

[2]The Department Grants Administration Manual is available for inspection at the Public Information Office of the several Department Regional Offices and available for purchase at the Government Printing Office, GPO Document No. 894-523.

L Budget revision procedures.
M Grant closeout: Suspension, and termination.
O Property.
Q Cost principles.

Subpart C—Occupational Safety and Health Direct Traineeships

§ 86.30 Nature and purpose of direct traineeships.

A direct traineeship is an award of funds directly from the Federal Government to an individual (herein called the "trainee") for his subsistence and other expenses during a period in which he is acquiring training (a) in the occupational safety and health professions, (b) for research relating to occupational safety and health, or (c) for teaching in occupational safety and health.

§ 86.31 Eligibility; minimum requirements.

In order to be eligible for an award under this subpart an applicant must:

(a) Have been accepted by a public or private institution for the purpose of the activity for which the traineeship is sought.

(b) Be a U.S. citizen, an alien lawfully admitted to the United States for permanent residence or a permanent resident of Guam, American Samoa, or the Trust Territory of the Pacific Islands.

[40 FR 29076, July 10, 1975, as amended at 47 FR 53012, Nov. 24, 1982]

§ 86.32 Application for direct traineeship.

An application for a direct traineeship under this subpart shall be submitted to the Secretary at such times and in such form and manner as he may prescribe.[1] In addition to the information supplied by the applicant in his application, such further information may be required as is necessary to determine his or her qualifications.

(Sec. 8(g), Public Health Service Act, 84 Stat. 1600 (29 U.S.C. 657(g)); sec. 21(a), Public Health Service Act, 84 Stat. 1612 (29 U.S.C. 670(a)))

[1] Applications and instructions may be obtained from the Procurement and Grants Office, Centers for Disease Control, Atlanta, GA 30333.

[40 FR 29076, July 10, 1975, as amended at 49 FR 38117, Sept. 27, 1984]

§ 86.33 Human subjects; animal welfare.

Where the application is for training at a non-Federal institution, no award may be made under this subpart unless said institution has complied with:

(a) 45 CFR Part 46 pertaining to the protection of human subjects; and

(b) Chapter 1-43 of the Department Grants Administration Manual[2] concerning animal welfare.

§ 86.34 Evaluation and award of direct traineeships.

Within the limits of funds available for such purpose and subject to the regulations of this part, the Secretary may award direct traineeships to those qualified applicants who are in his judgment best able to carry out the purpose of the traineeships taking into consideration the need for training in the area of study specified in the application.

§ 86.35 Payments.

(a) Individuals receiving awards shall be entitled to such stipends and allowances as the Secretary may designate, taking into account such factors as the needs of the program, the cost of living, and the availability of funds.

(Note: These are prescribed in Chapter 3-140 of the Department Grants Administration Manual[3]).

(b) Payments of stipends and allowances will, at the discretion of the Secretary, be made directly to the trainee or to the sponsoring institution for payment directly to the trainee.

§ 86.36 Duration and continuation.

Direct traineeship awards may be made for varying periods not in excess of 2 years. The Secretary may make one or more continuation awards for an additional period if he finds that satisfactory progress is being made toward accomplishment of the purpose of the initial traineeship award. Additional support may be provided on appropriate justification after expi-

[2] See footnote 2 to § 86.19.

ration of the period of support in the previous award.

§ 86.37 Terms and conditions.

All direct traineeship awards shall be subject to the following terms and conditions:

(a) Training must be carried out at an institution found by the Secretary to provide a well-rounded course of instruction in the particular area of training for which the traineeship is awarded.

(b) No direct traineeship may be utilized to compensate any trainee for personal services or employment on behalf of the United States or any person.

§ 86.38 Accountability.

Accountability for payments will be subject to such requirements as may be specified by the Secretary.

§ 86.39 Termination of direct traineeship.

(a) The Secretary may terminate a direct traineeship at any time upon request of the trainee.

(b) After reasonable notice to the trainee and an opportunity for the presentation of the trainee's views and relevant evidence, the Secretary may terminate any direct traineeship prior to the date it would otherwise expire upon a determination that the trainee's performance is unsatisfactory, that the trainee is no longer attending the sponsoring institution, or that he or she is unfit or unable to carry out the purpose of the traineeship.

(c) The views and evidence of the trainee shall be presented in writing unless the Secretary determines that an oral presentation is desirable.

PART 87—NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH RESEARCH AND DEMONSTRATION GRANTS

Sec.

87.1 To which programs does this regulation apply?
87.2 Definitions.
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87.4 For what purposes may grants be awarded?
87.5 What information must be included in the grant application?
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AUTHORITY: Sec. 8(g), 84 Stat. 1600 (29 U.S.C. 657(g)), sec. 508, 83 Stat. 803 (30 U.S.C. 957).

SOURCE: 46 FR 58676, Dec. 3, 1981, unless otherwise noted.

§ 87.1 To which programs does this regulation apply?

This regulation applies to research and demonstration project grants under: (a) Section 20(a)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(1)) for the support of studies related to occupational safety and health, and (b) section 501 of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951) for the support of health research in mining. These grants are awarded and administered by the National Institute for Occupational Safety and Health, Centers for Disease Control, of the Public Health Service.

§ 87.2 Definitions.

As used in this regulation:

"Demonstration project grant" means an award of funds to an eligible applicant to assist in meeting the cost of conducting a demonstration, either on a pilot or full-scale basis, of the technical or economic feasibility or application of a new or improved procedure, method, technique, or approach that will further the research purposes described in § 87.4.

"Principal investigator" for a research project, or "project director" for a demonstration project, means a single individual who is responsible for the scientific and technical direction of the project.

"Research project grant" means an award of funds to an eligible applicant to assist in meeting the costs of conducting an identified research activity or program, study, or experiment that will further the research purposes described in § 87.4.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

§ 87.3 Who is eligible to apply for a grant under this part?

Any public or private agency or institution is eligible to apply for a grant under this part, except Federal agencies or institutions not specifically authorized by law to receive such a grant.

§ 87.4 For what purposes may grants be awarded?

(a) The Occupational Safety and Health Act authorizes grants for research, experiments, and demonstrations relating to occupational safety and health, including studies of the psychological factors involved. This authority includes projects to develop innovative methods, techniques, and approaches for dealing with occupational safety and health problems.

(b) The Federal Mine Safety and Health Act authorizes grants for research projects designed to:

(1) Improve working conditions and practices affecting health in coal or other mines and to prevent occupational diseases originating in the mining industry.

(2) Develop epidemiological information to (i) identify and define positive factors involved in occupational diseases of miners, (ii) provide information on the incidence and prevalence of pneumoconiosis and other respiratory ailments of miners, and (iii) improve health standards.

(3) Develop techniques for the prevention and control of occupational diseases of miners, including tests for hypersusceptibility and early detection.

(4) Evaluate the effect on bodily impairment and occupational disability of miners afflicted with an occupational disease.

(5) Study the relationship between coal or other mine environments and occupational diseases of miners.

(6) Study matters involving the protection of life and the prevention of diseases in connection with persons who, although not miners, work with or around the products of coal or other mines in areas outside of such mines and under conditions which may adversely affect the health and well-being of such persons.

(7) Develop effective respiratory equipment.

§ 87.5 What information must be included in the grant application?

The application must contain a complete description of the objective of the project and the plan for carrying out the research or demonstration, the name and qualifications of the principal investigator or project director and principal staff members, the total resources and facilities that will be available, and a justification of the amount of grant funds requested.

§ 87.6 How will grant applications be evaluated and the grants awarded?

(a) The Secretary may award grants to those applicants whose approved projects will best promote the purposes of either the Occupational Safety and Health Act or the Federal Mine Safety and Health Act on the basis of an evaluation conducted by experts or consultants engaged for this purpose.

(b) This evaluation will take into account the scientific merit and significance of the project, the competency of the proposed staff in relation to the type of research or demonstration involved, the feasibility of the project, the likelihood of its producing meaningful results, the proposed project period, the adequacy of the applicant's resources available for the project, the amount of grant funds necessary for completion, and for mining grant applications, the recommendations of the Mine Health Research Advisory Committee.

(c) The Secretary may evaluate and approve two or more concurrent applications, each dealing with one or more specified aspects of the project, and make two or more concurrent grant awards for the project. This may be necessary when a project involves a number of different but related problems, activities, or disciplines which would require evaluation by different

groups, or when support for a project could be more effectively administered by separate handling of various aspects of the project.

§ 87.7 For what period of time will grants be awarded?

(a) The notice of grant award specifies how long the Secretary intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 3–5 years.

(b) Generally, the grant will initially be for 1 year and subsequent continuation awards will also be for 1 year at a time. A grantee must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be of such factors as the grantee's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by the Secretary that continued funding is in the best interest of the Federal Government.

(c) Neither the approval of any application, nor the award of any grant commits or obligates the Federal Government in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 87.8 How may a grantee use grant funds?

A grantee shall only spend funds it receives under this part according to the approved application and budget, the authorizing legislation, the terms and conditions of the grant award, the applicable cost principles specified in Subpart Q of 45 CFR Part 74, and the regulations of this part.

§ 87.9 Which other HHS regulations apply?

Several other regulations apply to grants under this part. These include, but are not limited to:

42 CFR Part 50, Subpart D—Public Health Service grant appeals procedure
45 CFR Part 16—Procedures of the Departmental Grant Appeals Board
45 CFR Part 46—Protection of human subjects
45 CFR Part 74—Administration of grants
45 CFR Part 75—Informal grant appeals procedures
45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964
45 CFR Part 81—Practice and procedure for hearing under Part 80 of this Title
45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance
45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance

(Sec. 8(g), Public Health Service Act, 84 Stat. 1600 (29 U.S.C. 657(g)); sec. 508, Public Health Service Act, 83 Stat. 803 (30 U.S.C. 957))

[49 FR 38117, Sept. 27, 1984]

SUBCHAPTER H—HEALTH ASSESSMENTS AND HEALTH EFFECTS STUDIES OF HAZARDOUS SUBSTANCES RELEASES AND FACILITIES

PART 90—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Sec.

90.1 Purpose and applicability.
90.2 Definitions.
90.3 Procedures for requesting health assessments.
90.4 Contents of requests for health assessments.
90.5 Acting on requests.
90.6 Notification of determination to conduct a health assessment in response to a request from the public.
90.7 Decision to conduct health effects study.
90.8 Conduct of health assessments and health effects studies.
90.9 Public health advisory.
90.10 Notice and comment period.
90.11 Reporting of results of health assessments and health effects studies.
90.12 Confidentiality of information.
90.13 Recordkeeping requirements.
90.14 Documentation and cost recovery.

AUTHORITY: 42 U.S.C. 9615; 42 U.S.C. 6939a(c).

SOURCE: 55 FR 5138, Feb. 13, 1990, unless otherwise noted.

§ 90.1 Purpose and applicability.

The provisions of this part set forth the policies and procedures of the Agency for Toxic Substances and Disease Registry (ATSDR) with respect to its conduct of health assessments and health effects studies under section 104(i) of Comprehensive Environmental Response, Compensation, and Liability Act, as amended by the Superfund Amendments and Reauthorization Act of 1986, and section 3019 of the Resource Conservation and Recovery Act. These provisions apply to ATSDR, as well as its contractors, agents, and those carrying out health assessments and health effects studies pursuant to agreements with ATSDR, such as other Federal agencies and States.

§ 90.2 Definitions.

"Administrator" means the Administrator of the Agency for Toxic Substances and Disease Registry or designee.

"ATSDR" means the Agency for Toxic Substances and Disease Registry, Public Health Service, U.S. Department of Health and Human Services.

"CERCLA" means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601 *et seq.*, Pub. L. 96-520), as amended by the Superfund Amendments and Reauthorization Act of 1986 (Pub. L. 99-499).

"EPA" means the U.S. Environmental Protection Agency.

"Facility" is defined in 42 U.S.C. 9601(9).

"Hazardous substance" is defined in 42 U.S.C. 9601(14). In addition, the term includes any pollutant or contaminant which the Administrator determines is appropriate for the purposes of carrying out his or her responsibilities under CERCLA.

"Health assessment" means the evaluation of data and information on the release of hazardous substances into the environment in order to assess any current or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects.

"Health effects study" means research, investigation, or study performed by ATSDR or other parties pursuant to an agreement with ATSDR to evaluate the health effects of exposure to hazardous substances at specific sites. This term includes, but is not limited to, epidemiological studies, exposure and disease registries, and health surveillance programs. This term does not include health assessments.

"Owner or operator" is defined in 42 U.S.C. 9601(20).

"Peer review" means review for scientific quality by a panel consisting of no less than three nor more than seven members, who shall be disinter-

ested scientific experts selected by the Administrator of ATSDR on the basis of their reputation for scientific objectivity and the lack of institutional ties with any person involved in the conduct of the study or research under review.

"Person" means an individual, firm, corporation, association, partnership, consortium, joint venture, commercial entity, United States Government, State, municipality, commission, political subdivision of a State, Indian tribe, or any interstate body.

"Pollutant or contaminant" is defined in 42 U.S.C. 9601(33).

"Public health advisory" is a statement by ATSDR containing a finding that a release poses a significant risk to human health and recommending measures to be taken to reduce exposure and eliminate or substantially mitigate the significant risk to human health.

"Release" is defined in 42 U.S.C. 9601(22).

§ 90.3 Procedures for requesting health assessments.

(a) ATSDR will accept requests to perform health assessments for a particular facility or release from any person or group of persons.

(b) All requests to ATSDR to perform health assessments should be addressed to: Assistant Administrator, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road NE., Atlanta, GA. 30333.

§ 90.4 Contents of requests for health assessments.

(a) Each request for a health assessment shall contain:

(1) The name, address (including zip code), and telephone number of the requestor;

(2) The organization or group the requestor represents, if any;

(3) The name, location, and description of the facility or release of concern;

(4) A statement providing information that individuals have been exposed to a hazardous substance and that the probable source is a release, or sufficient information to allow the Administrator to make such a finding;

(5) A statement requesting ATSDR to perform a health assessment.

(b) At his or her discretion, consistent with the requirements of CERCLA, the Administrator may decide not to require the preceding information be submitted with a request for a health assessment.

(c) Each request for a health assessment should include, where possible:

(1) Any other information pertaining to the facility or release, such as the nature and amount of the hazardous substances of concern or the identities of parties believed to be potentially responsible for the release;

(2) Potential pathways for human exposure, including a description of the media contaminated (e.g. soil, groundwater, air, etc.);

(3) The demographic nature and proximity of the potentially affected human population; and

(4) Other Federal, State, or local governmental agencies which were notified or that investigated the facility or release.

(d) This data collection has been reviewed and approved by OMB in accordance with the Paperwork Reduction Act and assigned the control number 0920–0204.

§ 90.5 Acting on requests.

(a) Upon receipt of a request for a health assessment submitted under this part, ATSDR will determine, in its discretion, whether or not there is a reasonable basis to justify conducting a health assessment. ATSDR will base this determination on, among other factors:

(1) Whether individuals have been exposed to a hazardous substance, for which the probable source of such exposure is a release;

(2) The location, concentration, and toxicity of the hazardous substances;

(3) The potential for further human exposure;

(4) The recommendations of other governmental agencies; and

(5) The ATSDR resources available and other ATSDR priorities, such as its responsibilities to conduct other health assessments and health effects studies.

(b) Where appropriate, ATSDR will request information from other Federal, State, and local governmental agencies, as well as other persons, pertaining to a facility or release which is the subject of a request from the public to ATSDR to conduct a health assessment.

(c) The requestor will be notified in writing of ATSDR's determination that either a health assessment will be performed, a health assessment will not be performed, or that further information concerning the facility or release is required before a decision can be made whether a health assessment will be performed.

(d) If a health assessment is not initiated in response to a request from the public, ATSDR shall provide a written explanation to the requestor of why a health assessment is not appropriate.

§ 90.6 Notification of determination to conduct a health assessment in response to a request from the public.

(a) Following a determination by ATSDR to conduct a health assessment in response to a request from the public, ATSDR shall notify in writing, at a minimum, the following parties of its intent to perform a health assessment:

(1) The U.S. Environmental Protection Agency;

(2) The appropriate State government environmental agency;

(3) The appropriate State and local health departments;

(4) The requestor;

(5) The owner or operator of the facility of concern, if their identity is readily available to ATSDR.

In addition, ATSDR will notify, in writing or by telephone, other potentially responsible parties, if their identity is readily available to ATSDR.

(b) At its discretion, ATSDR may notify any other persons which it feels may be affected by the release or have information pertaining to the release.

§ 90.7 Decision to conduct health effects study.

(a) ATSDR may decide, in its discretion, based upon the results of a health assessment or other available information, to conduct a health effects study for a particular site or sites. Such a decision may, in appropriate circumstances, be made prior to the completion of a health assessment for a site or sites. When deciding whether to conduct a health effects study, ATSDR will consider such factors as the results and recommendations of a health assessment for the site or sites and the need for additional information to determine whether individuals have been exposed to hazardous substances, the degree to which such exposure has occurred, and any possible health effects resulting from such exposure.

(b) Should ATSDR decide, in its discretion, to conduct a health effect study, it will notify the parties as specified in § 90.6.

§ 90.8 Conduct of health assessments and health effects studies.

(a) Any interested person or persons may submit data or information to ATSDR for it to consider in its conduct of a health assessment or a health effects study. In performing a health assessment or a health effects study, ATSDR will consider data and information it has independently generated or received from other parties, such as EPA, other Federal agencies, State and local governmental agencies, businesses, citizen organizations, and community groups.

(b) ATSDR may determine it is necessary to conduct a site visit in connection with a health assessment or health effects study. The ATSDR representative may allow the participation of any person in the site visit which he or she, at his or her discretion, determines will aid in the conduct of the health assessment or health effects study.

(c) In the event that the information necessary to perform a health assessment or health effects study is not readily available from other sources, ATSDR may arrange for sampling or additional data gathering at a facility or release for the limited purpose of determining the existence of current or potential health problems.

§ 90.9 Public health advisory.

ATSDR may issue a public health advisory based on the findings of a health assessment, health effects, study, or other ATSDR involvement.

§ 90.10 Notice and comment period.

Following internal review by ATSDR and external peer review of a draft final report of the results of a health effects study, ATSDR will publish a notice that the draft final report is available for public review and comment. At a minimum, the notice shall be published in at least one newspaper of general distribution in the local where the site is located. The notice shall describe how copies of the draft final report of the health effects study can be obtained and set a reasonable time period for interested persons to submit comments concerning the study. ATSDR may, at its discretion, respond in writing to comments it receives.

§ 90.11 Reporting of results of health assessments and health effects studies.

(a) ATSDR shall provide a report of the results of a health assessment or health effects study to EPA, the appropriate State and local governmental agencies, any person requesting ATSDR to conduct the health assessment, and parties potentially responsible for the release, if their identity is readily available to ATSDR. In addition, such reports shall be available to the general public upon request.

(b) In the event that ATSDR or its representatives conduct medical examinations of individuals in the course of a health effects study and the examination reveals a positive significant medical finding, the individual, and a physician if designated by the individual, will be promptly notified of that significant medical finding by ATSDR.

(c) A summary of the findings of all medical examinations for each individual will be sent by ATSDR to that individual.

(d) All studies and results of research conducted under this part (other than health assessments) shall be reported or adopted only after appropriate peer review.

§ 90.12 Confidentiality of information.

(a) ATSDR shall consider any medical information in individually identifiable form to be confidential information and shall release such information only in accordance with the Privacy Act (5 U.S.C. 552a) or other applicable Federal law.

(b) As provided under section 104(e)(7) of CERCLA, any records, reports, or information obtained from any person under this section shall be available to the public, except that upon a showing satisfactory to ATSDR by any person that records, reports, or information, or particular part thereof (other than health or safety effects data), to which any officer, employee, or representative of ATSDR has access under this part if made public would divulge information entitled to protection under the Trade Secrets Act (18 U.S.C. 1905), such information or particular portion thereof shall be considered confidential in accordance with the purposes of that section, except that such record, report, document, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out statutorily mandated duties.

(c) In submitting data to ATSDR, a person may designate the data which such person believes is entitled to protection under paragraph (b) of this section and submit such designated data separately from other data submitted under this part. A designation under this paragraph shall be made in writing to the Administrator. However, should ATSDR at any time question such designation, not less than 15 days notice to the person sumitting the information shall be given of the intention to remove such trade secret designation from such information. The person may submit a request to the Administrator to reconsider this intention and may provide additional information in support of the trade secret designation. The Administrator shall notify the person in writing of the decision which will become effective no sooner than 15 days after the date of such notice.

§ 90.13 Recordkeeping requirements.

(a) ATSDR shall maintain a record of all health assessments and health effects studies. The Administrator shall, at his or her discretion, determine the contents of the record. At a minimum, the record shall include:

(1) The final ATSDR report of the health assessment or health effects study;

(2) Nonconfidential data and other information upon which that report is based or which was considered by ATSDR;

(3) Nonconfidential data or other information submitted by interested persons pertaining to the health assessment or health effects study;

(4) The protocol for the health effects study;

(5) A list of the individuals responsible for external peer review of the report of a health effects study, their comments, and ATSDR's response to the comments; and

(6) For health effects study, the notice announcing the availability of a draft final report for public review and comment, all comments received in response to the notice, and any responses to the comments by ATSDR.

(b) The record may contain a confidential portion which shall include all information determined to be confidential by the Administrator under this part.

(c) The Administrator may determine other documents are appropriate for inclusion in the record for health assessments or health effects studies.

(d) Predecisional documents, including draft documents, are not documents upon which ATSDR bases its conclusions in health assessments or health effects studies, and are not usually included in the record for health assessments or health effects studies.

(e) The record for ATSDR health assessments and health effects studies will be available for review, upon prior request, at ATSDR headquarters in Atlanta, Georgia.

(f) Nothing in this section is intended to imply that ATSDR's decisions to conduct health assessments or health effects studies, or the reports of health assessments or health effects studies, are subject to judicial review.

§ 90.14 Documentation and cost recovery.

(a) During all phases of ATSDR health assessments and health effects studies, documentation shall be completed and maintained to form the basis for cost recovery, as specified in section 107 of CERCLA.

(b) Where appropriate, the information and reports compiled by ATSDR pertaining to costs shall be forwarded to the appropriate EPA regional office for cost recovery purposes.

SUBCHAPTERS I–J—[RESERVED]

SUBCHAPTER K—HEALTH RESOURCES DEVELOPMENT

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Authority: Secs. 215, 1602, 1625, Public Health Service Act (42 U.S.C. 216, 300o–1, 300r), unless otherwise noted.

Source: 42 FR 62270, Dec. 9, 1977, unless otherwise noted.

Subpart A—Project Grants for Public Medical Facility Construction and Modernization

§ 124.1 Applicability.

The regulations of this subpart are applicable to grants under section 1625 of the Public Health Service Act for construction and modernization projects designed to:

(a) Eliminate or prevent imminent safety hazards as defined by Federal, State or local fire, building, or life safety codes or regulations, or

(b) Avoid noncompliance with State or voluntary licensure or accreditation standards.

§ 124.2 Definitions.

As used in this subpart:

(a) "Act" means the Public Health Service Act, as amended.

(b) "Construction" means construction of new buildings and initial equipment of such buildings and, in any case in which it will help to provide a service not previously provided in the community, equipment of any buildings. It includes architect's fees, but excludes the cost of off-site improvements and, except with respect to

public health centers, the cost of the acquistion of land.

(c) "Cost" means the amount found by the Secretary to be necessary for construction or modernization under a project, except that such term does not include any amount found by the Secretary to be attributable to expansion of the bed capacity of any facility.

(d) "Equipment" means those items which are necessary for the functioning of the facility but does not include items of current operating expense such as food, fuel, pharmaceuticals, dressings, paper, printed forms, and housekeeping supplies.

(e) "Facility for long-term care" means a facility (including a skilled nursing care or intermediate care facility), providing inpatient care for convalescent or chronic disease patients who require skilled nursing or intermediate care and related medical services:

(1) Which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculosis patients) or is operated in connection with a hospital, or

(2) In which such care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(f) "Health systems agency" means an agency which has been conditionally or fully designated pursuant to section 1515 of the Act and 42 CFR Part 122.

(g) "Hospital" includes general, tuberculosis, and other types of hospitals, and related facilities such as laboratories, outpatient departments, nurses' home facilities, extended care facilities, facilities related to programs for home health services, self-care units, and central service facilities, operated in connection with hospitals, and education or training facilities for health professional personnel operated as an integral part of a hospital, but does not include any facility furnishing primarily domiciliary care.

(h) "Major repair" means those repairs to an existing building, excluding routine maintenance, which restore the building to a sound state, the cost of which is a least 10 percent of plant value or $200,000, whichever is greater. "Plant value" means the historic book value of the building at the time of application for assistance under this subpart.

(i) "Medical facility" means a hospital, public health center, outpatient medical facility, rehabilitation facility, or a facility for long-term care.

(j) "Modernization" means the alteration, expansion (excluding expansion which increases bed capacity), major repair, remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and the replacement of obsolete equipment of existing buildings, including energy conservation projects.

(k) "Outpatient medical facility" means a facility, located in or apart from a hospital, for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients):

(1) Which is operated in connection with a hospital, or

(2) In which patient care of a specialized nature (such as in an eye clinic, dental clinic, or ambulatory surgical center) is provided under the professional supervision of persons licensed to practice medicine or surgery in the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State, or

(3) Which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties, and which provides to its patients a reasonably full range of diagnostic and treatment services.

(l) "Public health center" means a publicly owned facility for the provision of public health services, including related facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

(m) "Quasi-public corporation" means a private, nonprofit corporation which has been formally given one or more governmental powers by a general-purpose unit of government to enable it to carry out its work.

(n) "Rehabilitation facility" means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through

an integrated program of medical evaluation and services, and psychological, social, or vocational evaluation and services, under competent professional supervision, and in the case of which the major portion of the required evaluation and services is furnished within the facility; and either the facility is operated in connection with a hospital, or all medical and related health services are prescribed by, or are under the general direction of persons licensed to practice medicine or surgery in the State.

(o) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(p) "State" means any one of the several States, the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

(q) "State health planning and development agency" or "State Agency" means the agency of a State government which has been conditionally or fully designated under section 1521 of the Act and 42 CFR Part 123.

(r) "Title" means a fee simple, or such other estate or interest in the project site (including a leasehold on which the rental does not exceed 4 percent of the value of the land) as the Secretary finds sufficient to assure undisturbed use and possession for the purpose of construction or modernization and operation of the project for a period of not less than twenty years.

(s) "Urban or rural poverty area" means a census tract, census county division, or minor civil division, as applicable, in which the percentage of the residents with incomes below the poverty level, as defined by the Secretary of Commerce is not less than the percentage derived in accordance with the following sentence. This percentage shall be derived so that the percentage of the total population of the United States residing in all such areas is equal to the percentage of the total population of the United States with incomes below such poverty level, plus five percent.

§ 124.3 Eligibility.

(a) *Eligible applicants.* A grant under section 1625 may only be made to a State or political subdivision of a State, including any city, town, county, borough, hospital district authority, or public or quasi-public corporation for a project described in paragraph (b) of this section for a medical facility owned, operated, or owned and operated by the State or political subdivision.

(b) *Eligible project.* A grant under section 1625 may be made only for a construction and/or modernization project designed to:

(1) Eliminate or prevent safety hazards which under Federal, State, and/or local fire, building or life safety codes or regulations, will, in the judgment of the Secretary result in one or more of the following:

(i) Loss of licensure for the facility.

(ii) Closing of all or a substantial part of the facility,

(iii) Loss of eligibility for reimbursement under Title XVIII or Title XIX of the Social Security Act; or

(2) Avoid noncompliance with State licensure or voluntary accreditation standards where noncompliance will, in the judgment of the Secretary, result in one or both of the following:

(i) Loss of licensure for the facility,

(ii) Loss of accreditation resulting in loss of eligibility for reimbursement under Title XVIII or Title XIX of the Social Security Act.

§ 124.4 Application.

An application for a grant under this subpart must be submitted directly to the Secretary at such time and in such form and manner as the Secretary may prescribe. The application must be executed by an individual authorized to act for the applicant and assume on behalf of the applicant the obligations imposed by the Act, this subpart, and the terms and conditions of the grant. The application must contain the following:

(a) A description of the site of the project.

(b) A full description, with all appropriate documentation, of:

(1) The imminent safety hazards, licensure and/or accreditation problems of the facility;

(2) The type and amount of assistance sought under this subpart;

(3) The construction of modernization project for which funds are sought, describing how it will remedy the problems described pursuant to paragraph (b)(1) of this section, with a complete schedule for the proposed construction or modernization; and

(4) How failure to remedy the problems described pursuant to paragraph (b) (1) of this section will affect the population served by the facility.

(c) In the case of a modernization project for continuation of existing health services, a finding by the State Agency of the continued need for such services. In the case of a construction or modernization project for new health services, a finding by the State Agency of the need for such services. The finding of need shall be based on the following criteria:

(1) In a State which has a program approved by the Secretary under section 1523(a)(4)(B) of the Act, a State certificate of need program, or a program under section 1122 of the Social Security Act, the State Agency shall use the criteria used in conducting reviews under such program. In a State which has more than one such program, the State Agency shall use the criteria of one of the programs and notify the Secretary of the program criteria used.

(2) In a State which does not have a program approved by the Secretary under section 1523(a)(4)(B) of the Act, a State certificate of need program or a program under section 1122 of the Social Security Act, the State Agency shall base its finding of need on the following criteria:

(i) Whether the propcsed project is needed or projected as necessary to meet the needs in the community in terms of health services required; *Provided,* That projects for highly specialized services (such as open-heart surgery, renal transplantation, or radiation therapy) which will draw from patient populations outside the community in which the project is situated will receive appropriate consideration;

(ii) Whether the proposed project can be adquately staffed and operated when completed;

(iii) Whether the proposed capital expenditure is economically feasible and can be accommodated in the patient charge structure of the health facility without unreasonable increases; and

(iv) Whether the project will foster cost containment or improved quality of care through improved effciency and productivity, including promotion of cost-effective factors such as ambulatory care, preventive health care services, home health care, and design and construction economies, or through increased competition between different health services delivery systems.

(d) [Reserved]

(e) An assurance that adequate financial support will be available for completion of the project, supported by a detailed project budget satisfactory to the Secretary which includes all existing and anticipated sources of funds for the project.

(f) An assurance that adequate financial support will be available for maintenance and operation of the project when completed, supported by budgets and detailed expenditure and revenue information satisfactory to the Secretary for both the facility and the applicant for the past three fiscal years and budget and projections of expenditures and revenue for the future three fiscal years. Where a certificate of need or a favorable finding under section 1122 of the Social Security Act is required in order for the project to operate and/or receive reimbursement from governmental programs for health services provided, assurance from the applicant satisfactory to the the Secretary that the applicant will submit, consistent with the provisions of § 124.5(d), any such required certificates of need and/or section 1122 finding.

(g) An assurance that the applicant would not be able to complete the project without the grant applied for supported by a description of all efforts to obtain funds needed to complete the project and the results of such efforts.

(h) An assurance that all times after the application is approved there will be made available in the facility or portion thereof to be constructed or modernized, a reasonable volume of services to persons unable to pay therefor. The applicant shall comply with the standards and procedures of 42 CFR 53.111, except as the Secretary may prescribe pursuant to section 1602(6) of the Act. The functions of the State Agency designated under section 604 of the Act under 42 CFR 53.111 will be performed by the Secretary, except to the extent they are otherwise assigned.

(i) An assurance that at all times after the application is approved the facility or portion thereof to be constructed or modernized will be made available to all persons residing or employed in the area served by the facility. The applicant shall comply with the standards and procedures of 42 CFR 53.113, except as the Secretary may prescribe pursuant to section 1602(6) of the Act. The functions of the State Agency designated under section 604 of the Act under 42 CFR 53.113 will be performed by the Secretary, except to the extent they are otherwise assigned.

(j) An assurance that title to the project site is or will be vested in one or more of the entities filing the application or in a public or other nonprofit entity which is to operate the facility on completion of the project, with such documentation as the Secretary may require.

(k) In the case of an application for construction or modernization of an outpatient medical facility, an assurance, supported by a written transfer agreement (or written documentation that such agreement will be obtained) with identified hospitals, that the services of a general hospital will be available to patients at such facility who are in need of hospital care.

(l) Evidence that:

(1) The appropriate health systems agency has been given the opportunity to review the application in accordance with section 1513(c) of the Act and the requirements of the Appendix to this subpart, with the result of any such review.

(2) The application has been reviewed in accordance with the applicable requirements of OMB Circular A-95.

(m) An analysis satisfactory to the Secretary and such other information and materials as the Secretary may require concerning the environmental impact of the proposed construction or modernization project.

(n) An assessment satisfactory to the Secretary of the project site in light of the considerations set forth in Executive Order 11296 (31 FR 10663, August 10, 1966) concerning the evaluation of flood hazards in locating Federally supported facilities.

(o) In the case of a project which involves the displacement of persons or businesses, an assurance that the applicant will comply with the applicable provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601 et seq.).

(p)(1) An assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a-276a-5, known as the Davis-Bacon Act); and

(2) An assurance that the following conditions and provisions will be included in all construction contracts:

(i) The provisions of "DHHS Requirements for Federally Assisted Construction Contracts Regarding Labor Standards and Equal Employment Opportunity," Form DHHS 514 (rev. July 1976) (issued by the Office of Grants and Procurement Management, U.S. Department of Health and Human Services) pertaining to the Davis-Bacon Act, the Contract Work Hours Standards Act, and the Copeland Act (Anti-Kickback) regulations except in the case of contracts in the amount of $2,000 or less; and pertaining to Executive Order 11246, September 24, 1965 (30 FR 12319), relating to nondiscrimination in construction contract employment except in the case of contracts in the amount of $10,000 or less, and

(ii) Representatives of the Secretary will have access at all reasonable times to work wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

(q) Such other information as the Secretary may require.

[42 FR 62270, Dec. 9, 1977, as amended at 49 FR 33021, Aug. 20, 1984]

§ 124.5 Grant evaluation and award.

(a)(1) Within the limits of funds available for such purpose, the Secretary may award grants under this subpart for project costs to applicants with approvable applications therefor which will, in his judgment, best promote the purposes of section 1625 of the Act, taking into consideration:

(i) The severity and seriousness of the safety hazard, licensure or accreditation problem or problems.

(ii) The relative need of the population to be served for the services to be provided, including the availability of alternatives for meeting the need.

(iii) The financial need of the applicant.

(iv) The extent to which the facility will serve persons below the poverty level, as determined by the Secretary of Commerce.

(v) The extent to which the project will foster cost containment or improve the quality of care through enhanced efficiency and productivity.

(2) Priority for funding shall be based on the extent to which services will be made available relative to the cost of the project.

(b) The amount of any grant under this subpart may not exceed 75 percent of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may, as determined by the Secretary, cover up to 100 percent of such costs.

(c) If an applicant has not entered into a legally enforceable fixed price contract for the project for which funds are awarded under this subpart within 180 days of the date of the grant award, the grant award will automatically become null and void.

(d) Where a grant has been awarded to an applicant under this subpart on the condition that any applicable certificates of need and section 1122 finding required under § 124.4(f) will be provided, if such certificates and finding have not been received by the Secretary within 180 days of the grant award, the grant award will automatically become null and void.

§ 124.6 Grant payments.

Grant payments shall be made to the applicant in accordance with the requirements of Subpart K of 45 CFR Part 74.

§ 124.7 Use of grant funds.

Any funds granted pursuant to this subpart, as well as funds assured by the applicant for the project, shall be expended solely for carrying out the approved project in accordance with section 1625 of the Act, the regulations of this subpart, the terms and conditions of the grant award, and the applicable cost principles prescribed by Subpart Q of 45 CFR Part 74.

§ 124.8 Grantee accountability.

(a) *Records requirements.* (1) Applicants who have received Federal assistance under this subpart shall maintain, in accounting records which are separate from the records of all other funds, records which fully disclose the following:

(i) The amount of all payments received from the Secretary under this subpart,

(ii) Amounts and sources of all funds, in addition to funds received under this subpart, applied to the construction or modernization project funded under this subpart,

(iii) Disposition of all funds for the construction or modernization project funded under this subpart,

(iv) Total cost of the project approved under this subpart, and

(2) Upon request, applicants shall make such records, books, papers, or other documents available to the Secretary and the Comptroller General of the United States or any of their duly authorized representatives which, in their opinion, may be related or pertinent to the grant under this subpart.

(b) *Annual financial statement.* An applicant who receives grant assistance under this subpart shall, not later than 120 days after the end of its fiscal year, unless a longer period is approved by the Secretary for good cause shown, file an annual financial statement which meets the requirements of section 1634 of the Act.

§ 124.9 Nondiscrimination.

(a) Attention is called to the requirements of Title VI of the Civil Rights Act of 1964 (78 Stat. 252, 42 U.S.C. 2000d et seq.) and in that particular section 601 of such Act which provides that no person in the United States shall, on the grounds of race, color or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such Title VI, which is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR Part 80).

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing section 504 has been issued (45 CFR Part 84 (42 FR 22676, May 4, 1977)).

(c) All portions and services of the entire facility for the construction or modernization of which, or in connection with which aid under the Act is sought must be made available without discrimination on account of creed and the applicant may not discriminate against any qualified person on account of creed with respect to the privilege of professional practice in the facility.

(d) Attention is also called to the requirements of Title IX of the Education amendments of 1972 and in particular to section 901 of such Act (20 U.S.C. 1681) which provides that no person in the United States shall, on the basis of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance (45 CFR Part 86).

(e) Each construction contract is subject to the condition that the applicant shall comply with the requirements of section 321 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, as amended, which provides that alcohol abusers and alcoholics who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their alcohol abuse or alcoholism by any private or public general hospital that receives support in any form from any federally funded program.

(f) Each construction contract is subject to the condition that the applicant shall comply with the requirements of section 407 of the Drug Abuse Office and Treatment Act of 1972, as amended, which provides that drug abusers who are suffering from medical conditions shall not be discriminated against because of their drug abuse or drug dependence, by any private or public general hospital that receives support in any form from any federally funded program.

§ 124.10 Additional conditions.

The Secretary may impose additional conditions prior to or at the time of any grant award when in the Secretary's judgment such conditions are necessary to assure or protect advancement of the project in accordance with the purposes of the Act and the regulations of this subpart or the conservation of grant funds.

§ 124.11 Applicability of 45 CFR Part 74.

The provisions of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in Subpart A of that Part 74, except to the extent inconsistent with this subpart. The relevant provisions of the following subparts of Part 74 shall also apply to

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grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:
A General.
B Cash depositories.
C Bonding and insurance.
F Grant-related income.
G Matching and cost sharing.
L Budget revision procedures.
M Grant closeout, suspension, and termination.
O Property.
P Procurement standards.
Q Cost principles.

Subparts B–E—[Reserved]

Subpart F—Reasonable Volume of Uncompensated Services to Persons Unable to Pay

AUTHORITY: 42 U.S.C. 216; 42 U.S.C. 300s(3).

SOURCE: 52 FR 46031, Dec. 3, 1987, unless otherwise noted.

§ 124.501 Applicability.

(a) The provisions of this subpart apply to any recipient of Federal assistance under Title VI or XVI of the Public Health Service Act that gave an assurance that it would make available, in the facility or portion of the facility constructed, modernized or converted with that assistance, a reasonable volume of services to persons unable to pay for the services.

(b) The provisions of this subpart apply to facilities for the following periods:

(1) *Facilities assisted under Title VI.* Except as otherwise herein provided, a facility assisted under Title VI of the Act shall provide uncompensated services at the annual compliance level required by § 124.503(a) for:

(i) Twenty years after the completion of construction, in the case of a facility for which the Secretary provided grant assistance under section 606 of the Act; or

(ii) The period from completion of construction until the amount of a direct loan under sections 610 and 623 of the Act, or the amount of a loan with respect to which the Secretary provided a guarantee and interest subsidy under section 623 of the Act, is repaid, in the case of a facility for which such a loan was made.

(iii) "Completion of construction" means:

(A) The date on which the Secretary determines the facility was opened for service;

(B) If the opening date is not available, it means the date on which the Secretary approved the final part of the facility's application for assistance under Title VI of the Act;

(C) If the date of final approval is not available, it means whatever date the Secretary determines most reasonably approximates the date of final approval.

(2) *Facilities assisted under Title XVI.* The provisions of this subpart apply to a facility assisted under Title XVI of the Act at all times following the Secretary's approval of the facility's application for assistance under Title XVI, except that if the facility does not at the time of that approval provide health services, the assurance applies at all times following the facility's initial provision of health services to patients, as determined by the Secretary.

§ 124.502 Definitions.

As used in this subpart—

(a) "Act" means the Public Health Service Act, as amended.

(b) "Allowable credit" for services provided to a specific patient means the lesser of the facility's usual charge for those services, or the usual charge multiplied by the percentage which the total allowable cost as reported by the facility in the facility's preceding fiscal year under Title XVIII of the Social Security Act (42 U.S.C. 1395, *et seq.*) and the implementing regulations (42 CFR Part 413) bears to the facility's total patient revenues for the year.

(c) "Applicant" means a person who requests uncompensated services or on whose behalf uncompensated services are requested.

(d) "CPI" means the National Consumer Price Index for medical care.

(e) "Facility" means an entity that received assistance under Title VI or XVI of the Act and provided an assurance that it would provide a reasonable

ble volume of services to persons unable to pay for the services.

(f) "Federal assistance" means assistance received by the facility under Title VI or Title XVI of the Act and any assistance supplementary to that Title VI or Title XVI assistance received by the facility under any of the following acts: the District of Columbia Medical Facilities Construction Act of 1968, 82 Stat. 631 (Pub. L. 90-457); the Public Works Acceleration Act of 1962 (42 U.S.C. 2641, *et seq.*); the Public Works and Economic Development Act of 1965 (42 U.S.C. 3121, *et seq.*); the Appalachian Regional Development Act of 1965, as amended (40 U.S.C. App.); the Local Public Works Capital Development and Investment Act of 1976 (Pub. L. 94-369). In the case of a loan guaranteed by the Secretary with an interest subsidy, the amount of Federal assistance under Title VI or Title XVI for a fiscal year is the total amount of the interest subsidy that the Secretary will have paid by the close of that fiscal year, as well as any other payments which the Secretary has made as of the beginning of the fiscal year on behalf of the facility in connection with the loan guarantee or the direct loan which has been sold.

(g) "Fiscal year" means the facility's fiscal year.

(h) "Nursing home" means a facility which received Federal assistance for and operates as a "facility for long-term care" as defined at, as applicable, section 645(h) or section 1624(6) of the Act.

(i) "Operating costs" for any fiscal year means the total operating expenses of a facility as set forth in an audited financial statement, minus the amount of reimbursement, if any, received (or if not received, claimed) in that year under Titles XVIII and XIX of the Social Security Act.

(j) "Persons unable to pay" means persons who meet the eligibility criteria set out in § 124.505.

(k) "Request for uncompensated services" means any indication by or on behalf of an individual seeking services of the facility of the individual's inability to pay for services. A request for uncompensated services may be made at any time, including following institution of a collection action against the individual.

(l) "Secretary" means the Secretary of Health and Human Services or [his or her] delegatee.

(m) "Uncompensated services" means:

(1) For facilities other than those certified under § 124.513, § 124.514, or § 124.515, health services that are made available to persons unable to pay for them without charge or at a charge which is less than the allowable credit for those services. The amount of uncompensated services provided in a fiscal year is the total allowable credit for services less the amount charged for the services following an eligibility determination. Excluded are services provided more than 96 hours following notification to the facility by a peer review organization that it disapproved the services under section 1155(a)(1) or section 1154(a)(1) of the Social Security Act.

(2) For facilities certified under § 124.513, § 124.514, or § 124.515, services as defined in paragraph (m)(1) of this section and services that are made available to persons unable to pay for them under programs described by the documentation provided under § 124.513(c)(2) or § 124.514(c)(2), as applicable, or pursuant to the terms of the applicable grant or agreement as provided in § 124.515. Excluded are services reimbursed by Medicare, Medicaid or other third party programs, including services for which reimbursement was provided as payment in full, and services provided more than 96 hours following notification to the facility by a peer review organization that it disapproved the services under section 1155(a)(1) or section 1154(a)(1) of the Social Security Act.

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987]

§ 124.503 Compliance level.

(a) *Annual compliance level.* Subject to the provisions of this subpart, a facility is in compliance with its assurance to provide a reasonable volume of services to persons unable to pay if it provides for the fiscal year uncompensated services at a level not less than the lesser of—

(1) Three percent of its operating costs for the most recent fiscal year for which an audited financial statement is available;

(2) Ten percent of all Federal assistance provided to or on behalf of the facility, adjusted by a percentage equal to the percentage change in the CPI between the year in which the facility received assistance or 1979, whichever is later, and the most recent year for which a published index is available.

(b) *Deficits.* If in any fiscal year a facility fails to meet its annual compliance level, it shall provide uncompensated services in an amount sufficient to make up that deficit in subsequent years, and its period of obligation shall be extended until the deficit is made up.

(1) *Types of deficits.* For purposes of determining the timing and amount of any deficit make-up, there are two types of deficits:

(i) *Justifiable deficits.* A justifiable deficit is one in which the facility did not meet its annual compliance level due to either financial inability (as determined under § 124.511(c)) or, although otherwise in compliance with this subpart, a lack of eligible applicants for uncompensated services during the fiscal year.

(ii) *Noncompliance deficits.* A noncompliance deficit is one in which the facility failed to meet its annual compliance level due to noncompliance with this subpart.

(2) *Timing of deficit make-up*—(i) *Justifiable deficits.* (A) A facility assisted under Title VI of the Act may make up a justifiable deficit at any time during its period of obligation or in the year (or years, if necessary) immediately following its period of obligation.

(B) A facility assisted under Title XVI of the Act is not required to make up a justifiable deficit.

(ii) *Noncompliance deficits.* (A) A facility must begin to make up a noncompliance deficit in the fiscal year following the finding of noncompliance by the Secretary.

(B) A facility which claimed financial inability under § 124.509(a)(2)(iii) and is found by the Secretary, pursuant to § 124.511(c), to have been financially able to provide uncompensated services in the year in which the deficit was incurred shall begin to make up the deficit beginning in the fiscal year following the Secretary's finding.

(C) A facility required to make up a noncompliance deficit but which is determined by the Secretary, pursuant to § 124.511(c), to be financially unable to do so in the year following the Secretary's finding of noncompliance shall make up the deficit in accordance with a schedule set by the Secretary.

(3) *Deficit make-up amount.* (i) The amount of a deficit in any fiscal year is the difference between the facility's annual compliance level for that year and the amount of uncompensated services provided in that year.

(ii) The amount of a justifiable deficit must be adjusted by a percentage equal to the percentage change in the CPI between the CPI available in the fiscal year in which the deficit was incurred and the CPI available in the fiscal year in which it was made up.

(iii) An amount equal to the result of dividing the amount of any noncompliance deficit for a fiscal year by the number of years of obligation remaining and adjusting it by a percentage equal to the percentage change in the CPI between the CPI available in the fiscal year in which the deficit was incurred and the CPI available in the fiscal year in which it was made up shall be added to a facility's annual compliance level for each fiscal year following the fiscal year of the finding of noncompliance.

(4) *Affirmative action plan for precluding future deficits.* Except where a facility reports to the Secretary in accordance with § 124.509(a)(2)(iii) that it was financially unable to provide uncompensated services at the annual compliance level, a facility that fails to meet its annual compliance level in any fiscal year shall, in the following year, develop and implement a plan of action that can reasonably be expected to enable the facility to meet its annual compliance level. Such actions may include special notice to the community through newspaper, radio, and television, or expansion of service to Category B persons. The Secretary may require changes to the plan.

Where a facility fails to comply with this section, the Secretary may require it to make up the deficit in the fiscal year following the year in which it was required to institute the plan.

(c) *Excesses.* (1) Except for facilities certified under § 124.513, § 124.514, or § 124.515, if a facility provides in a fiscal year uncompensated services in an amount exceeding its annual compliance level, it may apply the amount of excess to reduce its annual compliance level in any subsequent fiscal year. The facility may use any excess amount to reduce its annual compliance level only if the services in excess of the annual compliance level are provided in accordance with the requirements of this subpart.

(2) *Calculation and adjustment of excess.* (i) The amount of an excess in uncompensated services in any fiscal year is the difference between the amount of uncompensated services the facility provided in that year and the facility's annual compliance level for that year.

(ii) The amount of any excess compliance applied to reduce a facility's annual compliance level must be adjusted by a percentage equal to the percentage change in the CPI between the CPI available in the fiscal year in which the facility provided the excess, and the CPI available in the fiscal year in which the facility applies the excess to reduce its annual compliance level or satisfy its remaining obligation.

(3) Except as provided in subparagraph (1) of this paragraph, a facility assisted under Title VI may in any fiscal year apply the amount of excess credited under this paragraph to satisfy the remainder of its obligation to provide uncompensated services. A facility's remaining obligation is determined as follows:

(i) Where the annual compliance level in such fiscal year is established under paragraph (a)(2) of this section, the remaining obligation is:

(A) For grant assistance, 10 percent of each grant under obligation, multiplied by the number of years remaining in its period of obligation, adjusted as provided for in paragraph (a)(2) of this section, plus any deficits required to be made up and less any unused excesses accrued in prior years; and

(B) For loan assistance, the facility's annual compliance level multiplied by the number of years remaining in the scheduled life of the loan, plus the sum of 10 percent of each yearly cumulative total of additional interest subsidy or other payments (which the Secretary will have made in connection with the guaranteed loan or a direct loan which has been sold) in each subsequent year remaining in the scheduled life of the loan, plus any deficits required to be made up, and less any unused excesses accrued in prior years; or

(ii) Where the annual compliance level in such fiscal year is established under paragraph (a)(1) of this section, the remaining obligation is the average of the facility's annual compliance levels in the previous three years, multiplied by the number of years remaining in its period of obligation, plus any deficits required to be made up under this section, and less any unused excesses accrued in prior years.

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987]

§ 124.504 Notice of availability of uncompensated services.

(a) *Published notice.* A facility shall publish in a newspaper of general circulation in its area notice of its uncompensated services obligation before the beginning of its fiscal year. The notice shall include:

(1) The plan of allocation the facility proposes to adopt;

(2) The amount of uncompensated services the facility intends to make available in the fiscal year or a statement that the facility will provide uncompensated services to all persons unable to pay who request uncompensated services;

(3) An explanation, if the amount of uncompensated services the facility intends to make available in a fiscal year is less than the annual compliance level. If a facility has satisfied its remaining uncompensated services obligation since the last published notice under this paragraph, or will satisfy the remaining obligation during the

fiscal year, the explanation must include this information; and

(4) A statement inviting interested parties to comment on the allocation plan.

(b) *Posted notice.* (1) The facility shall post notices, which the Secretary supplies in English and Spanish, in appropriate areas in the facility, including but not limited to the admissions areas, the business office, and the emergency room.

(2) If in the service area of the facility the "usual language of households" of ten percent or more of the population according to the most recent figures published by the Bureau of the Census is other than English or Spanish, the facility shall translate the notice into that language and post the translated notice on signs substantially similar in size and legibility to and posted with those supplied under paragraph (b)(1) of this section.

(3) The facility shall make reasonable efforts to communicate the contents of the posted notice to persons who it has reason to believe cannot read the notice.

(c) *Individual written notice.* (1) In any period during a fiscal year in which uncompensated services are available in the facility, the facility shall provide individual written notice of the availability of uncompensated services to each person who seeks services in the facility on behalf of himself or another. The individual written notice must:

(i) State that the facility is required by law to provide a reasonable amount of care without or below charge to people who cannot afford care;

(ii) Set forth the criteria the facility uses for determining eligibility for uncompensated services (in accordance with the financial eligibility criteria and the allocation plan);

(iii) State the location in the facility where anyone seeking uncompensated services may request them; and

(iv) State that the facility will make a written determination of whether the person will receive uncompensated services, and the date by or period within which the determination will be made.

(2) The facility shall provide the individual written notice before providing services, except where the emergency nature of the services provided makes prior notice impractical. If this exception applies, the facility shall provide the individual written notice to the next of kin or to the patient as soon as practical, but not later than when first presenting a bill for services.

(3) The facility shall make reasonable efforts to communicate the contents of the individual written notice to persons who it has reason to believe cannot read the notice.

§ 124.505 Eligibility criteria.

(a) A person unable to pay for health services is a person who—

(1) Is not covered, or receives services not covered, under a third-party insurer or governmental program, except where the person is not covered because the facility fails to participate in a program in which it is required to participate by § 124.603(c);

(2) Falls into one of the following categories:

(i) *Category A*—A person whose annual individual or family income, as applicable, is not greater than the current poverty line issued by the Secretary pursuant to 42 U.S.C. 9902 that applies to the individual or family. The facility shall provide uncompensated services to persons in Category A without charge.

(ii) *Category B*—A person whose annual individual or family income, as applicable, is greater than but not more than twice the poverty line issued by the Secretary pursuant to 42 U.S.C. 9902 that applies to the individual or family. If persons in Category B are included in the allocation plan, the facility shall provide uncompensated services to these persons without charge, or in accordance with a schedule of charges as specified in the allocation plan; and

(3) Requests services within the facility's allocation plan in effect at the time of the request.

(b) For purposes of determining eligibility for uncompensated services, revisions of the poverty line are effective 60 days from the date of their publication in the FEDERAL REGISTER.

(c) A person is eligible for uncompensated services if the person's individual or family annual income, as applicable, is at or below the level established under paragraph (a)(2) when calculated by either of the following methods:

(1) Multiplying by four the person's or family's income, as applicable, for the three months preceding the request for uncompensated services;

(2) Using the person's or family's income, as applicable, for the twelve months preceding the request for uncompensated services.

§ 124.506 Allocation of services; plan requirement.

(a)(1) A facility shall provide its uncompensated services in accordance with a plan that sets out the method by which the facility will distribute its uncompensated services among persons unable to pay. The plan must:

(i) State the type of services that will be made available;

(ii) Specify the method, if any, for distributing those services in different periods of the year;

(iii) State whether Category B persons will be provided uncompensated services, and if so, whether the services will be available without charge or at a reduced charge;

(iv) If services will be made available to Category B persons at a reduced charge, specify the method used for reducing charges, and provide that this method is applicable to all persons in Category B; and

(v) Provide that the facility provides uncompensated services to all persons eligible under the plan who request uncompensated services.

(2) A facility must adopt an allocation plan that meets the requirements of paragraph (a) by publishing the plan in a newspaper of general circulation in its area. The plan may take effect no earlier than 60 days following the date of publication.

(b)(1) If in any fiscal year a facility fails to adopt and publish a plan in accordance with paragraph (a), it shall provide uncompensated services in accordance with the last plan it published in a newspaper of general circulation in its area.

(2) If no plan was previously published in accordance with paragraph (a)(2), the facility must provide uncompensated services without charge to all applicants in Category A and Category B who request service in the facility. This requirement applies until the facility ceases to provide uncompensated services under § 124.508 or until an allocation plan published in accordance with paragraph (a)(2) of this section becomes effective.

(c) A facility may revise its allocation plan during the fiscal year by publishing the revised plan in a newspaper of general circulation in the area it serves. A revised plan may take effect no earlier than 60 days following the date of publication.

§ 124.507 Written determinations of eligibility.

(a) Determinations of eligibility must be in writing, be made in accordance with this section, and a copy of the determination must be provided to the applicant promptly.

(b) *Content of determinations*—(1) *Favorable determinations.* A determination that an applicant is eligible must indicate:

(i) That the facility will provide uncompensated services at no charge or at a specified charge less than the allowable credit for the services;

(ii) The date on which services were requested;

(iii) The date on which the determination was made;

(iv) The applicant's individual or family income, as applicable, and family size; and

(v) The date on which services were or will be first provided to the applicant.

(2) *Conditional determinations.* (i) As a condition to providing uncompensated services, a facility may:

(A) Require the applicant to furnish any information that is reasonably necessary to substantiate eligibility; and

(B) Require the applicant to apply for any benefits under third party insurer or governmental programs to which he/she is or could be entitled upon proper application.

(ii) A conditional determination must:

(A) Comply with paragraph (b)(1) of this section; and

(B) State the condition(s) under which the applicant will be found eligible.

(iii) When a facility determines that the condition(s) upon which a conditional determination was made has been met, or will not be met, it shall make a favorable determination or denial on the request, as appropriate, in accordance with this section.

(3) *Denials.* A facility must provide to each applicant denied the uncompensated services requested, in whole or in part, a dated statement of the reasons for the denial.

(c) *Timing of determinations*—(1) *Preservice determinations.* (i) Facilities other than nursing homes shall make a determination of eligibility within two working days following a request for uncompensated services which is made before receipt of outpatient services or before discharge for inpatient services;

(ii) Nursing homes shall make a determination of eligibility within ten working days, but no later than two working days following the date of admission, following a request for uncompensated services made prior to admission.

(2) *Postservice determinations.* All facilities shall make a determination of eligibility not later than the end of the first full billing cycle following a request for uncompensated services which is made after receipt of outpatient services, discharge for inpatient services, or admission for nursing home services.

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987]

§ 124.508 Cessation of uncompensated services.

(a) *Facilities not certified under § 124.513, 124.514, or § 124.515.* Where a facility, other than a facility certified under § 124.513, § 124.514, or § 124.515, has maintained the records required by § 124.510(a) and determines based thereon that it has met its annual compliance level for the fiscal year or the appropriate level for the period specified in its allocation plan, it may, for the remainder of that year or period:

(1) Cease providing uncompensated services;

(2) Cease providing individual notices in accordance with § 124.504(c);

(3) Remove the posted notices required by § 124.504(b); and

(4) Post an additional notice stating that it has satisfied its obligation for the fiscal year or appropriate period and when additional uncompensated services will be available.

(b) *Facilities certified under § 124.514.* Where a facility certified under § 124.514 has maintained the records required by § 124.510(c) and determines based thereon that it has met its compliance level, under § 124.514(d), for the fiscal year, it may, for the remainder of the fiscal year:

(1) Cease providing uncompensated services; and

(2) Discontinue providing notice pursuant to § 124.514(b)(2).

§ 124.509 Reporting requirements.

(a) *Facilities not certified under § 124.513, § 124.514, or § 124.515*—(1) *Timing of reports.* (i) A facility shall submit to the Secretary a report to assist the Secretary in determining compliance with this subpart once every three fiscal years, on a schedule to be prescribed by the Secretary.

(ii) A facility shall submit the required report more frequently than once every three years under the following circumstances:

(A) If the facility determines that in the preceding fiscal year it did not provide uncompensated services at the annual compliance level, it shall submit a report.

(B) If the Secretary determines, and notifies the facility in writing that a report is needed for proper administration of the program, the facility shall submit a report within 90 days after receiving notice from the Secretary, or within 90 days after the close of the fiscal year, whichever is later.

(iii) Except as specified in paragraph (a)(1)(ii)(B) of this section, the reports required by this section shall be submitted within 90 days after the close of the fiscal year, unless a longer

riod is approved by the Secretary r good cause.

(2) *Content of report.* The report ust include the following informaon in a form prescribed by the Secrery:

(i) Information that the Secretary escribes to permit a determination whether a facility has met the nual compliance level for the fiscal ars covered by the report;

(ii) The date on which the notice reired by § 124.504(a) was published, d the name of the newspaper that rinted the notice;

(iii) If the amount of uncompensatd services provided by the facility in e preceding fiscal year was lower an the annual compliance level, an xplanation of why the facility did not eet the required level. If the facility laims that it failed to meet the reuired compliance level because it was nancially unable to do so, it shall exlain and provide documentation precribed by the Secretary;

(iv) If the facility is required to ubmit an affirmative action plan, a opy of the plan.

(v) Other information that the Secetary prescribes.

(3) *Institution of suit.* Not later than 0 days after being served with a sumnons or complaint the facility shall otify the HHS Regional Health Adinistrator[1] for the Region in which t is located of any legal action rought against it alleging that it has ailed to comply with the requirements of this subpart.

(b) *Facilities certified under § 124.513.* A facility certified under § 124.513 shall comply with paragraph (a)(3) of this section and shall submit within 90 days after the close of its fiscal year, as appropriate:

(1) A certification, signed by the responsible official of the facility, that there has been no material change in the factors upon which the certification was based; or

(2) A certification, signed by the responsible official of the facility and supported by appropriate documentation, that there has been a material change in the factors upon which the certification was based.

(c) *Facilities certified under § 124.514.* A facility certified under § 124.514 shall comply with paragraph (a)(3) of this section and shall submit within 90 days after the close of its fiscal year, as appropriate:

(1)(i) A certification, signed by the responsible official of the facility, that there has been no material change in the factors upon which the certification was based; or

(ii) A certification, signed by the responsible official of the facility and supported by appropriate documentation, that there has been a material change in the factors upon which the certification was based; and

(2) A certification, signed by the responsible official of the facility, of the amount of uncompensated services provided in the previous fiscal year.

(d) *Facilities certified under § 124.515.* A facility certified under § 124.515 shall submit such reports as are required by the terms of its grant under section 329 or 330 or by its agreement under section 334 of the Act, as applicable, at such intervals as the Secretary may require.

(Approved by the Office of Management and Budget under Control Number 0915-0077)

[52 FR 46031, Dec. 3, 1987, as amended at 52 FR 48362, Dec. 21, 1987; 54 FR 52939, Dec. 26, 1989]

§ 124.510 Record maintenance requirements.

(a) *Facilities not certified under § 124.513, § 124.514, or § 124.515.* (1) A facility shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance with the requirements of this subpart in any fiscal year, including:

(i) Any documents from which the information required to be reported under § 124.509(a) was obtained;

(ii) Accounts which clearly segregate uncompensated services from other accounts; and

(iii) Copies of written determinations of eligibility under § 124.507.

[1] The addresses of the HHS Regional Offices are set out in 45 CFR 5.31.

(2) A facility shall retain the records maintained pursuant to paragraph (a)(1) for three years after submission of the report required by § 124.509(a)(1), except where a longer period is required by the Secretary, or until 180 days following the close of the Secretary's assessment investigation under § 124.511(b), whichever is less.

(3) A facility shall, within 60 days of the end of each fiscal year, determine the amount of uncompensated services it provided in that fiscal year. Documents that support the facility's determination shall be made available to the public on request. If a report is or will be filed under § 124.509(a)(1), a facility may respond to a request by providing a copy of the report to the requester.

(b) *Facilities certified under § 124.513 or § 124.514.* A facility certified under § 124.513 or § 124.514 shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance with the applicable requirements of this subpart in any fiscal year, including those documents submitted to the Secretary under § 124.513(c) or § 124.514(c). A facility shall maintain these records for three years, except where a longer period is required as a result of an investigation by the Secretary. In such cases, records must be kept until 180 days following the close of the Secretary's assessment investigation under § 124.511(b).

(c) *Facilities certified under § 124.515.* A facility certified under § 124.515 shall maintain the records required by its grant under section 329 or section 330 or its agreement under section 334 of the Act, as applicable, for such period of time as the grant agreement may require.

(Information collection requirements found in paragraphs (a) and (b) with respect to § 124.513 were approved by the Office of Management and Budget under control number 0915-0103)

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987]

§ 124.511 Investigation and determination of compliance.

(a) *Complaints.* A complaint that a facility is out of compliance with the requirements of this subpart may be filed with the Secretary by any person.

(1) A complaint is considered to be filed with the Secretary on the date the following information is received in the Office of the HHS Regional Health Administrator for the Region in which the facility is located:

(i) The name and address of the person making the complaint or on whose behalf the complaint is made;

(ii) The name and location of the facility;

(iii) The date or approximate date on which the event occurred; and

(iv) A statement of what actions the complainant considers to violate the requirements of this subpart.

(2) The Secretary promptly provides a copy of the complaint to the facility named in the complaint.

(3) When the Secretary investigates a facility, the facility, including a facility certified under § 124.513, § 124.514, or § 124.515, shall provide to the Secretary on request any documents, records and other information concerning its operation that relate to the requirements of this subpart. A facility will be presumed to be out of compliance with its assurance unless it supplies documentation sufficient to show compliance with the applicable provisions of this subpart.

(4) Section 1627 of the Act provides that if the Secretary dimisses a complaint or the Attorney General has not brought an action for compliance within six months from the date on which the compliant is filed, the person filing it may bring a private action to effectuate compliance with the assurance. If the Secretary determines that he/she will be unable to issue a decision on a complaint or otherwise take appropriate action within the six month period, the Secretary may, based on priorities for the disposition of complaints that are established to promote the most effective use of enforcement resources, or on the request of the applicant, dismiss the complaint without a finding as to

compliance prior to the end of the six month period, but no earlier than 45 days after the complaint is filed.

(b) *Assessments.* The Secretary periodically investigates and assesses facilities to ascertain compliance with the requirements of this subpart, including certification of the amount of uncompensated services provided in a fiscal year or years, and provides guidance and prescribes corrective action to correct noncompliance.

(1) *Compliance after February 1, 1988.*

(i) The Secretary may certify that a facility has substantially complied with its assurance for a fiscal year or years, and such certification shall establish that the facility provided the amount of uncompensated services certified for the period covered by the certification.

(ii) A certification of substantial compliance shall be based on the amount properly claimed by the facility pursuant to § 124.509(a), utilizing procedures determined by the Secretary to be sufficient to establish that the facility has substantially complied with its assurance for the period covered by the certification. The procedures will include examination of individual account data to the extent deemed necessary by the Secretary.

(iii) A certification of substantial compliance will be made where the Secretary determines that, for the period covered by the certification, the facility provided uncompensated services to eligible persons who had equal opportunity to apply therefor. In making this determination, the Secretary will consider, in descending order of importance, whether—

(A) Corrective action prescribed pursuant to § 124.512(b) has been taken by the facility;

(B) Any noncompliance with the requirements of this subpart may be remedied by corrective action under § 124.512(b);

(C) The facility had procedures in place that complied with the requirements of §§ 124.504(c), 124.505, 124.507, 124.509, 124.510, 124.513(b)(2), 124.514(b)(2), and 124.515, as applicable, and systematically correctly followed such procedures.

(2) *Compliance prior to February 1, 1988.* The Secretary will determine the amount of creditable services provided prior to the effective date of these rules using the compliance standards applicable under the rules as promulgated on May 18, 1979, based on procedures determined by the Secretary to be sufficient to establish that the facility provided such amounts of uncompensated services in the period(s) being assessed.

(c) *Determinations of financial inability.* In determining whether a facility was or is financially able to meet its annual compliance level, the Secretary will consider any comments submitted by interested parties. In making this determination, the Secretary will consider factors such as:

(1) The ratio of revenues to expenses;

(2) The occupancy rate;

(3) The ratio of current assets to current liabilities;

(4) The average cost per patient day;

(5) The number of days of operating expenses in accounts payable;

(6) The number of days of revenues in accounts receivable;

(7) The sinking fund (or depreciation fund) balance;

(8) The debt coverage ratio; and

(9) The availability of restricted or unrestricted funds (such as an endowment) available for charitable use.

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987; 53 FR 5576, Feb. 25, 1988]

§ 124.512 Enforcement.

(a) If the Secretary finds, based on his/her investigation under § 124.511, that a facility did not comply with the requirements of this subpart, the Secretary may take any action authorized by law to secure compliance, including but not limited to, voluntary agreement or a request to the Attorney General to bring an action against the facility for specific performance.

(b) A facility, including a facility certified under § 124.513 or § 124.514, that has denied uncompensated services to any person because it failed to comply with the requirements of this subpart will not be in compliance with its assurance until it takes whatever steps

are necessary to remedy fully the noncompliance, including:

(1) Provision of uncompensated services to applicants improperly denied;

(2) Repayment of amounts improperly collected from persons eligible to receive uncompensated services; and

(3) Other corrective actions prescribed by the Secretary.

(c) The Secretary may disallow all of the uncompensated services claimed in a fiscal year where the Secretary finds that the facility was in substantial noncompliance with its assurance because it failed to:

(1) Have a system for providing notice to eligible persons as required by § 124.504(c), § 124.513(b)(2) or § 124.514(b)(2), as applicable;

(2) Comply with the applicable reporting requirements of § 124.509;

(3) Have a system for maintaining records of uncompensated services provided in accordance with § 124.510; or

(4) Take corrective action prescribed pursuant to paragraph (b) of this section.

(d) In the absence of a finding of substantial compliance or substantial noncompliance in a fiscal year, the Secretary may disallow uncompensated services claimed by a facility in that fiscal year to the extent that the Secretary finds that such services are not documented as uncompensated services under § 124.510 or are subject to disallowance under § 124.513(d) or § 124.514(d), as applicable.

§ 124.513 Public facility compliance alternative.

(a) *Effect of certification.* The Secretary may certify a facility which meets the requirements of paragraphs (b) and (c) of this section as a "public facility". A facility which is so certified is not required to comply with this subpart except as otherwise herein provided.

(b) *Criteria for qualification.* A public facility may qualify for certification under this section if all of the following criteria are met:

(1) It is a facility which is owned and operated by a unit of State or local government or a quasi-public corporation as defined at 42 CFR 124.2(m).

(2) It provides health services without charge or at a substantially reduced rate to persons who are determined by the facility to qualify therefor under a program of discounted health services. A "program of discounted health services" must provide for financial and other objective eligibility criteria and procedures, including notice prior to nonemergency service, that assure effective opportunity for all persons to apply for and obtain a determination of eligibility for such services, including a determination prior to service where requested; *provided that,* such criteria and procedures are not required where the facility makes all services available to all persons at no or nominal charge.

(3)(i) It received, for the three most recent fiscal years, at least 10 percent of its total operating revenue (net patient revenue plus other operating revenue, exclusive of any amounts received, or if not received, claimed, as reimbursement under Titles XVIII and XIX of the Social Security Act) from State and local tax appropriations or other State and local government revenues, or from a quasi-public corporation as defined at 42 CFR 124.2(m), to cover operating deficits attributable to the provision of discounted services; or

(ii) If provided, in each of the three most recent fiscal years, uncompensated services under this subpart or under programs described by the documentation provided under § 124.513(c)(2) in an amount not less than twice the annual compliance level computed under § 124.503(a).

(c) *Procedures for certification.* To be certified under this section, a facility must submit to the Secretary, in addition to other materials that the Secretary may from time to time require, copies of the following:

(1) Audited financial statements or official State or local government documents (such as annual reports or budget documents), for the three most recent fiscal years, sufficient to show that the facility meets the criteria in paragraph (b)(3)(i) or (ii).

(2) A complete description of its program(s) of discounted health services, including charging and collection policies of the facility, and eligibility

criteria and notice and determination procedures used under its program(s) of discounted services.

(d) *Period of effectiveness.* (1) A certification by the Secretary under this section remains in effect until withdrawn. The Secretary may disallow credit under this subpart when the Secretary determines that there has been a material change in any factor upon which certification was based or substantial noncompliance with this subpart. The Secretary may withdraw certification where the change or noncompliance has not been adequately remedied or otherwise continues.

(2) *Deficits*—(i) *Title VI-assisted facilities with assessed deficits.* Where a facility assisted under Title VI of the Act has been assessed as having a deficit under § 124.503(b) that has not been made up prior to certification under this section, the facility may make up that deficit by either—

(A) Demonstrating to the Secretary's satisfaction, that it met the requirements of paragraph (b) of this section for each year in which a deficit was assessed; or

(B) Providing an additional period of service under this section on the basis of one (or portion of a) year of certification for each year (or portion of a year) of deficit assessed. The period of obligation applicable to the facility under § 124.501(b) shall be extended until the deficit is made up in accordance with the preceding sentence.

(ii) *Title VI-assisted facilities which have not been assessed.* Where any period of compliance under this subpart of a facility assisted under Title VI of the Act has not been assessed, the facility will be presumed to have no allowable credit for such period. The facility may either—

(A) Make up such deficit in accordance with paragraph (d)(2)(i) of this section; or

(B) Submit an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (d)(2)(i) of this section.

(iii) *Title XVI-assisted facilities.* (A) A facility assisted under Title XVI of the Act which has an assessed deficit which was not made up prior to certification under this section shall make up that deficit in accordance with paragraph (d)(2)(i)(A) of this section. If it cannot make the showing required by that paragraph, it shall make up the deficit when its certification under this section is withdrawn.

(B) A facility assisted under Title XVI of the Act whose compliance with this subpart has not been completely assessed will be presumed to have no allowable credit for the unassessed period. The facility may make up the deficit by—

(*1*) Following the procedure of subparagraph (d)(2)(iii)(A) of this section; or

(*2*) Submitting an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (d)(2)(iii)(A) of this section.

(Approved by the Office of Management and Budget under control number 0915-0103)

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987]

§ 124.514 Compliance alternative for facilities with small annual obligations.

(a) *Effect of certification.* The Secretary may certify a facility which meets the requirements of paragraphs (b) and (c) of this section as a "facility with a small annual obligation." A facility which is so certified is not required to comply with this subpart except as otherwise herein provided.

(b) *Criteria for qualification.* A facility may qualify for certification under this section if all of the following criteria are met:

(1)(i) Title VI-assisted facilities. (A) For the facility's fiscal year in which this section becomes effective, the level, computed under § 124.503(c) (3), divided by the number of years remaining in its period of obligation (including an additional year or portion of a year for each year or portion of a year in which a deficit was incurred and has not been made up), is not more than $10,000;

(B) For a subsequent fiscal year, the level computed under subparagraph (A) of this paragraph, is at or less than $10,000, adjusted by a percentage equal to the percentage change in the CPI available in the year in which this section becomes effective and the most recent year for which a published index is available.

(ii) *Title XVI-assisted facilities.* (A) For the facility's fiscal year in which this section becomes effective, the level under § 124.503(a), plus the amount of any noncompliance deficits which have not been made up, is at or less than $10,000.

(B) For a subsequent fiscal year, the level, computed under subparagraph (A) of this paragraph, is at or less than $10,000, adjusted as provided in paragraph (b) (i) (B) of this section.

(2) It provides health services without charge or at a substantially reduced rate to persons who are determined by the facility to qualify threrefor under a program of discounted health services. A "program of discounted health services" must provide for financial and other objective eligibility criteria and procedures, including notice prior to nonemergency service, that assure effective opportunity for all persons to apply for and obtain a determination of eligibility for such services, including a determination prior to service where requested; *Provided that,* such criteria and procedures are not required where the facility makes all services available to all persons at no or nominal charge.

(c) *Procedures for certification.* To be certified under this section, a facility must submit to the Secretary, in addition to other materials that the Secretary may from time to time require, a complete description of its program(s) of discounted health services, including charging and collection policies of the facility, and eligibility criteria and notice and determination precedures used under its program(s) of discounted services.

(d) *Period of effectiveness.* A certification by the Secretary under this section remains in effect until withdrawn. During the period in which such certification is in effect, the facility must provide uncompensated services in an amount not less than the level applicable under paragraph (b)(1) of this section for each fiscal year. The Secretary may disallow credit under this subpart when the Secretary determines that there has been a material change in any factor upon which certification was based or substantial noncompliance with this subpart. The Secretary may withdraw certification where the change or noncompliance cannot be or has not been adequately remedied or noncompliance otherwise continues.

(e) *Deficits.* (1) Where the compliance level of a facility assisted under Title VI of the Act is computed under paragraph (b)(1)(i)(A) of this section as including additional year(s) or a portion of a year, the facility's period of obligation under this subpart shall be extended by such additional period until certification is withdrawn.

(2) Where a facility has been assessed as having a deficit under § 124.503(b) that has not been made up prior to withdrawal of certification under this section or fails to provide services as required by paragraph (d) of this section, the facility must make up the deficit in accordance with § 124.503(b) following withdrawal of certification.

(Approved by the Office of Management and Budget under Control Number 0915-0077)

[52 FR 46031, Dec. 3, 1987, as amended at 53 FR 48362, Dec. 21, 1987; 54 FR 52939, Dec. 26, 1989]

§ 124.515 Compliance alternative for community health centers, migrant health centers and certain National Health Service Corps sites.

(a) *Period of effectiveness.* For each fiscal year for which a facility that receives a grant to operate a community health center under section 330 of the

Act or a migrant health center under section 329 of the Act is in substantial compliance with the terms and conditions of such grant relating to the provision of services at a discount, the facility shall be certified as having met its annual compliance level in accordance with the requirements of this subpart and shall not be required otherwise to comply with the requirements of this subpart for that fiscal year. This provision also applies to any facility that has signed a memorandum of agreement with the Secretary under section 334 of the Act if the services provided by the National Health Service Corps professional(s) assigned pursuant to that agreement constitute all of the medical services provided by the facility.

(b) *Deficits*—(1) *Title VI-assisted facilities with assessed deficits.* Where a facility assisted under Title VI of the Act has been assessed as having a deficit under § 124.503(b) that has not been made up prior to certification under this section, the facility may make up that deficit by either—

(i) Demonstrating to the Secretary's satisfaction that it met the requirements of paragraph (a) of this section for each year in which a deficit was assessed; or

(ii) Providing an additional period of service under this section on the basis of one (or portion of a) year of certification for each year (or portion of a year) of deficit assessed. The period of obligation applicable to the facility under § 124.501(b) shall be extended until the deficit is made up in accordance with the preceding sentence.

(2) *Title VI-assisted facilities which have not been assessed.* Where any period of compliance under this subpart of a facility assisted under Title VI of the Act has not been assessed, the facility will be presumed to have no allowable credit for such period. The facility may either—

(i) Make up such deficit in accordance with paragraph (b)(1) of this section; or

(ii) Submit an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (b)(1) of this section.

(3) *Title XVI-assisted facilities.* (i) A facility assisted under Title XVI of the Act which has an assessed deficit which was not made up prior to certification under this section shall make up that deficit in accordance with paragraph (b)(1)(i) of this section. If it cannot make the showing required by that paragraph, it shall make up the deficit when it is no longer certified under this section.

(ii) A facility assisted under Title XVI of the Act whose compliance with this subpart has not been completely assessed will be presumed to have no allowable credit for the unassessed period. The facility may make up the deficit by—

(A) Following the procedure of paragraph (b)(3)(i) of this section; or

(B) Submitting an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (b)(3)(i) of this section.

(Approved by the Office of Management and Budget under Control Number 0915-0077)

[52 FR 46031, Dec. 3, 1987, as amended at 52 FR 48362, Dec. 21, 1987; 54 FR 52939, Dec. 26, 1989]

§ 124.516 Agreements with State agencies.

(a) Where the Secretary finds that it will promote the purposes of this subpart and the State agency is able and willing to do so, the Secretary may enter into an agreement with an agency of a State to assist in administering this subpart in the State. An agreement may be terminated by the Secretary or the State agency on 60 days notice.

(b) Under an agreement the State agency will provide any assistance the Secretary requests in any one or more of the following areas, as set out in the agreement:

(1) Investigation of complaints regarding noncompliance;

(2) Monitoring compliance of facilities with the requirements of this subpart;

(3) Review of reports submitted under § 124.509, including affirmative action plans;

(4) Making initial decisions for the Secretary with respect to compliance, subject to appeal by any party to the Secretary, or review by the Secretary on the Secretary's initiative; and

(5) Application of any sanctions available to it under State law (such as license revocation or termination of State assistance) against facilities determined to be out of compliance with the requirements of this subpart.

(c) Nothing in this subpart precludes any State from taking any action authorized by State law regarding the provision of uncompensated services by facilities in the State as long as the action taken does not prevent the Secretary from enforcing the requirements of this subpart.

Subpart G—Community Service

AUTHORITY: Sec. 215, 1525, 1602(6), Public Health Service Act as amended; 58 Stat 690, 88 Stat. 2249, 2259; 42 U.S.C. 216, 300m–4, 300o–1(6).

SOURCE: 44 FR 29379, May 18, 1979, unless otherwise noted.

§ 124.601 Applicability.

The provisions of this subpart apply to any recipient of Federal assistance under Title VI or XVI of the Public Health Service Act that has given an assurance that it would make the facility or portion thereof assisted available to all persons residing (and, in the case of Title XVI assisted applicants, employed), in the territorial area it serves. This assurance is referred to in this subpart as the "community service assurance."

§ 124.602 Definitions.

As used in this subpart:

"Act" means the Public Health Service Act, as amended.

"Facility" means the an entity that received assistance under Title VI or Title XVI of the Act and provided a community service assurance.

"Fiscal year" means facility's fiscal year.

"Secretary" means the Secretary of Health and Human Services or his delegatee.

"Service area" means the geographic area designated as the area served by the facility in the most recent State plan approved by the Secretary under Title VI, except that, at the request of the facility, the Secretary may designate a different area proposed by the facility when he determines that a different area is appropriate based on the criteria in 42 CFR 53.1(d).

"State agency" means the agency of a state fully or conditionally designated by the Secretary as the State health planning and development agency of the State under section 1521 of the Act.

§ 124.603 Provision of services.

(a) *General.* (1) In order to comply with its community service assurance, a facility shall make the services provided in the facility or portion thereof constructed, modernized, or converted with Federal assistance under Title VI or XVI of the Act available to all persons residing (and, in the case of facilities assisted under Title XVI of the Act, employed) in the facility's service area without discrimination on the ground of race, color, national origin, creed, or any other ground unrelated to an individual's need for the service or the availability of the needed service in the facility. Subject to paragraph (b) (concerning emergency services) a facility may deny services to persons who are unable to pay for them unless those persons are required to be provided uncompensated services under the provisions of Subpart F.

(2) A person is residing in the facility's service area for purposes of this section if the person:

(i) Is living in the service area with the intention to remain there permanently or for an indefinite period;

(ii) Is living in the service area for purposes of employment; or

(iii) Is living with a family member who resides in the service area.

(b) *Emergency services.* (1) A facility may not deny emergency services to any person who resides (or, in the case of facilities assisted under Title XVI of the Act, is employed) in the facility's service area on the ground that the person is unable to pay for those services.

(2) A facility may discharge a person that has received emergency services, or may transfer the person to another facility able to provide necessary services, when the appropriate medical personnel determine that discharge or transfer will not subject the person to a substantial risk of deterioration in medical condition.

(c) *Third party payor programs.* (1) The facility shall make arrangements, if eligible to do so, for reimbursement for services with:

(i) Those principal State and local governmental third-party payors that provide reimbursement for services that is not less than the actual costs, as determined in accordance with accepted cost accounting principles; and

(ii) Federal governmental third-party programs, such as medicare and medicaid.

(2) The facility shall take any necessary steps to insure that admission to and services of the facility are available to beneficiaries of the governmental programs specified in paragraph (c)(1) of this section without discrimination or preference because they are beneficiaries of those programs.

(d) *Exclusionary admissions policies.* A facility is out of compliance with its community service assurance if it uses an admission policy that has the effect of excluding persons on a ground other than those permitted under paragraph (a) of this section. Illustrative applications of this requirement are described in the following paragraphs:

(1) A facility has a policy or practice of admitting only those patients who are referred by physicians with staff privileges at the facility. If this policy or practice has the effect of excluding persons who reside (or for Title XVI facilities, are employed) in the community from the facility because they do not have a private family doctor with staff privileges at the facility, the facility would not be in compliance with its assurance. The facility is not required to abolish its staff physician admissions policy as a usual method for admission. However, to be in compliance with its community service assurance it must make alternative arrangements to assist area residents who would otherwise be unable to gain admission to obtain services available in the facility. Examples of alternative arrangements a facility might use include:

(i) Authorizing the individual's physician, if licensed and otherwise qualified, to treat the patient at the facility even though the physician does not have staff privileges at the facility;

(ii) For those patients who have no physician, obtaining the voluntary agreement of physicians with staff privileges at the facility to accept referrals of such patients, perhaps on a rotating basis;

(iii) If an insufficient number of physicians with staff privileges agree to participate in a referral arrangement, requiring acceptance of referrals as a condition to obtaining or renewing staff privileges;

(iv) Establishing a hospital-based primary care clinic through which patients needing hospitalization may be admitted; or

(v) Hiring or contracting with qualified physicians to treat patients who do not have private physicians.

(2) A facility, as required, is a qualified provider under the Title XIX medicaid program, but few or none of the physicians with staff privileges at the facility or in a particular department or sub-department of the facility will treat medicaid patients. If the effect is that some medicaid patients are excluded from the facility or from any service provided in the facility, the facility is not in compliance with its community service assurance. To be in compliance a facility does not have to require all of its staff physicians to accept medicaid. However, it must take steps to ensure that medicaid beneficiaries have full access to all of its available services. Examples of steps that may be taken include:

(i) Obtaining the voluntary agreement of a reasonable number of physicians with staff privileges at the facility and in each department or sub-department to accept referral of medicaid patients, perhaps on a rotating basis;

(ii) If an insufficient number of physicians with staff privileges agree to participate in a referral arrangement, requiring acceptance of referrals as a condition to obtaining or renewing staff privileges;

(iii) Establishing a clinic through which medicaid beneficiaries needing hospitalization may be admitted; or

(iv) Hiring or contracting with physicians to treat medicaid patients.

(3) A facility requires advance deposits (pre-admission or pre-service deposits) before admitting or serving patients. If the effect of this practice is that some persons are denied admission or service or face substantial delays in gaining admission or service solely because they do not have the necessary cash on hand, this would constitute a violation of the community service assurance. While the facility is not required to forego the use of a deposit policy in all situations, it is required to make alternative arrangements to ensure that persons who probably can pay for the services are not denied them simply because they do not have the available cash at the time services are requested. For example, many employed persons and persons with other collateral do not have savings, but can pay hospital bills on an installment basis, or can pay a small deposit. Such persons may not be excluded from admission or denied services because of their inability to pay a deposit.

§ 124.604 Posted notice.

(a) The facility shall post notices, which the Secretary supplies in English and Spanish, in appropriate areas of the facility, including but not limited to the admissions area, the business office and the emergency room.

(b) If in the service area of the facility the "usual language of households" of ten percent or more of the population, according to the most recent figures published by the Bureau of the Census, is other than English or Spanish, the facility shall translate the notice into that language and post the translated notice on signs substantially similar in size and legibility to, and posted with, those supplied under paragraph (a).

(c) The facility shall make reasonable efforts to communicate the contents of the posted notice to persons who it has reason to believe cannot read the notice.

§ 124.605 Reporting and record maintenance requirements.

(a) *Reporting requirements.*—(1) *Timing of reports.*—(i) A facility shall submit to the Secretary a report to assist the Secretary in determining compliance with this subpart once every three fiscal years, on a schedule to be prescribed by the Secretary. The report required by this section shall be submitted not later than 90 days after the end of the fiscal year, unless a longer period is approved by the Secretary for good cause shown.

(ii) A facility shall also submit the required report whenever the Secretary determines, and so notifies the facility in writing, that a report is needed for proper administration of the program. In this situation the facility shall submit the report specified in this section for the filing of reports, within 90 days after receiving notice from the Secretary, or within 90 days after the close of the fiscal year, whichever is later.

(2) *Content of report.* The report must be submitted on a form prescribed by the Secretary and must include information that the Secretary prescribes to permit a determination of whether a facility has met its obligations under this subpart.

(3) The facility shall provide a copy of any report to the HSA for the area when submitting it to the Secretary.

(4) *Institution of suit.* Not later than 10 days after being served with a summons or complaint, the applicant shall notify the Regional Health Administrator for the Region of HHS in which it is located of any legal action brought against it alleging that it has

failed to comply with the requirements of this subpart.[1]

(b) *Record maintenance requirements.* (1) A facility shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance requirements of this subpart in any fiscal year, including documents from which information required to be reported under paragraph (a) of this section was obtained. A facility shall maintain these records until 180 days following the close of the Secretary's investigation under § 124.606(a).

§ 124.606 Investigation and enforcement.

(a) *Investigations.* (1) The Secretary periodically investigates the compliance of facilities with the requirements of this subpart, and investigates complaints.

(2)(i) A complaint is filed with the Secretary on the date on which the following information is received in the Office of the Regional Health Administrator for the Region of HHS in which the facility is located:

(A) The name and address of the person making the complaint or on whose behalf the complaint is made;

(B) The name and location of the facility;

(C) The date or approximate date on which the event complained of occurred, and

(D) A statement of what actions the complainant considers to violate the requirements of this subpart.

(ii) The Secretary promptly provides a copy of the complaint to each facility named in the complaint.

(3) When the Secretary investigates a facility, the facility shall provide to the Secretary on request any documents, records and other information concerning its operations that relate to the requirements of this subpart.

(4) The Act provides that if the Secretary dismisses a complaint or the Attorney General has not brought an action for compliance within six months from the date on which the complaint is filed, the person filing it may bring a private action to effectuate compliance with the assurance. If the Secretary determines that he will be unable to issue a decision on a complaint or otherwise take appropriate action within the six month period, he may, based on priorities for the disposition of complaints that are established to promote the most effective use of enforcement resources, or on the request of the complainant, dismiss the complaint without a finding as to compliance prior to the end of the six month period, but no earlier than 45 days after the complaint is filed.

(b) *Enforcement.* (1) If the Secretary finds, based on his investigation under paragraph (a) of this section, that a facility did not comply with the requirements of this subpart, he may take any action authorized by law to secure compliance, including but not limited to voluntary agreement or a request to the Attorney General to bring an action against the facility for specific performance.

(2) If the Secretary finds, based on his investigation under paragraph (a) of this section, that a facility has limited the availability of its services in a manner proscribed by this subpart, he may, in addition to any other action that he is authorized to take in accordance with the Act, require the facility to establish an effective affirmative action plan that in his judgment is designed to insure that its services are made available in accordance with the requirements of this subpart.

§ 124.607 Agreements with State agencies.

(a) Where the Secretary finds that it will promote the purposes of this subpart, and the State agency is able and willing to do so, he may enter into an agreement with the State agency for the State agency to assist him in administering this subpart in the State.

(b) Under an agreement, the State agency will provide the Secretary with any assistance he requests in any one or more of the following areas, as set out in the agreement:

(1) Investigation of complaints of noncompliance;

[1] The addresses of the Regional Office of HHS are set out in 45 CFR 5.31.

(2) Monitoring the compliance of facilities with the requirements of this subpart;

(3) Review of affirmative action plans submitted under § 124.606(b);

(4) Review of reports submitted under § 124.605;

(5) Making initial decisions for the Secretary with respect to compliance, subject to appeal by any party to the Secretary or review by the Secretary on his own initiative; and

(6) Application of any sanctions available to it under State law (such as license revocation or termination of State assistance) against facilities determined to be out of compliance with the requirements of this subpart.

(c) A State agency may use funds received under section 1525 of the Act to pay for expenses incurred in the course of carrying out this agreement.

(d) Nothing in this subpart precludes any State from taking any action authorized by State law regarding the provision of services by any facility in the State as long as the action taken does not prevent the Secretary from enforcing the requirements of this subpart.

Appendix to Subpart G—Interim Procedures and Criteria for Review by Health Systems Agencies of Applications Under Section 1625 of the Public Health Service Act

In performing reviews under section 1513(e) of the Public Health Service Act (42 U.S.C. 3001-2(c)) of applications for grants under section 1625 of the Act, health systems agencies shall use the procedures and criteria stated below. A health systems agency may not conduct such reviews until the procedures and criteria to be used in conducting the reviews have been adopted by the agency and published in newspapers of general circulation within the health service area or other public information channels.

PROCEDURES

The procedures adopted and utilized by a health systems agency for conducting reviews of applications for grants under section 1625 of the Act shall include at least the following: 1. Except as provided below, notification of the beginning of a review within seven days of the receipt by the health systems agency of the application. Where the application was received by the health systems agency prior to publication of this subpart in the Federal Register, notification must be made within seven days of the date on which the health systems agency adopts its procedures and criteria. The notification shall include the proposed schedule for the review, the period within which a public hearing during the course of the review may be requested (which must be a reasonable period from the transmittal of the written notification required above), and the manner in which notification will be provided of the time and place of any hearings so requested. Written notification to members of the public may be provided through newspapers of general circulation in the area and public information channels. Notification to the applicant whose application is being reviewed and all other applicants for assistance under section 1625 of the Act providing health service in the health service area shall be by mail (which may be as part of a newsletter). The health systems agency must simultaneously notify the Federal funding agency of the beginning of the review.

2. Schedules for reviews which provide that such reviews shall not exceed 60 days from the date of notification made in accordance with paragraph 1 of this section to the date of the written findings made in accordance with paragraph 4 of this section. This does not preclude a health systems agency from conducting its review in less than 60 days.

3. Provision for applicants to submit to the health systems agency (in such form and manner as the agency shall require) such information as the agency deems necessary in order to conduct its review.

4. Written findings which state the basis for the approval or disapproval of the application by the health systems agency. Such findings shall be sent to the applicant, the State health planning and development agency (or agencies), and the Secretary, and shall be available to other upon request.

5. Access by the general public to all such applications reviewed by the health systems agency and to all other written materials pertinent to the agency review.

6. Public hearings in the course of agency review, if requested by one or more persons directly affected by the review. For purposes of this paragraph, a "person directly affected by the review" is as defined in 42 CFR 122.306(a)(7).

CRITERIA

The specific criteria adopted and utilized by a health systems of this agency to conduct reviews of applications for grants under section 1625 of the Act shall include at least the following:

1. The relationship of the health services of the facility to the applicable health systems plan and annual implementation plan.

2. The relationship of the health services of the facility to the long-range development plan (if any) of the applicant.

3. The need that the population served or to be served by the facility has for the health services of such facility.

4. The availability of alternative, less costly, or more effective methods of providing the health services which the facility provides.

5. The relationship of the health services provided by the facility to the existing health care system of the area.

6. The availability of resources (including health manpower, management personnel, and funds for capital and operating needs) for the provision of services by the facility and the availability of alternative uses of such resources for the provision of other health services.

7. The special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service area in which the entities are located or in adjacent health service areas. Such entities may include medical and other health professions schools, multidisciplinary clinics, and other speciality centers.

8. The special needs and circumstances of health maintenance organizations for which assistance may be provided under Title XIII.

9. The costs and methods of the proposed construction or modernization, including the costs and methods of energy provision.

10. The probable impact of the project reviewed on the applicant's costs of providing health services.

Subpart H—Recovery of Grant Funds

AUTHORITY: The provisions of this subpart H are issued under sections 609 and 1622 of the Public Health Service Act as amended 98 Stat. 112 (42 U.S.C. 291i and 300s–1a).

SOURCE: 51 FR 7939, Mar. 7, 1986, unless otherwise noted.

§ 124.701 Applicability.

The provisions of this subpart apply to facilities with respect to which grant funds were paid for construction or modernization—

(a) Under Title VI or XVI of the Public Health Service Act; or

(b) Pursuant to the authority of the Secretary under any of the following statutes:

(1) The Public Works Acceleration Act of 1962, Pub. L. 87–658 (42 U.S.C. 2641 et seq.);

(2) The District of Columbia Medical Facilities Construction Act of 1968, 82 Stat. 631 (Pub. L. 90–457);

(3) The Appalachian Regional Development Act of 1965, as amended (40 U.S.C. App.).

§ 124.702 Definitions.

As used in this subpart—

"Act" means the Public Health Service Act.

"Department" means the Department of Health and Human Services.

"Expected useful life" means the period of time during which the structure may reasonably be expected to perform the function for which it was designed or intended.

"Facility" means a facility with respect to which grant funds were paid under any of the authorizations listed in § 124.701.

"Fiscal year" means the facility's fiscal year.

"Nonprofit", as applied to any facility, means a facility that is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

"State agency" means (1) in the case of a facility with respect to which a grant was made under Title VI of the Public Health Service Act or any of the statutes listed in § 124.701(b), the State agency designated pursuant to section 604 of the Public Health Service Act or its successor agency, and (2) in the case of a facility with respect to which a grant was made under Title XVI of the Public Health Service Act, the State health planning and development agency designated pursuant to Title XV of the Public Health Service Act.

"Then value" means the value of the facility on the date the facility is sold, transferred or ceases to be used for a

permissible use as described in § 124.704.

§ 124.703 Federal right of recovery.

(a) If any facility is at any time within 20 years after the completion of the grant-assisted construction or modernization sold or transferred to any entity which is either not qualified for a grant under the statute pursuant to which the grant was awarded or not approved as a transferee by the State agency, the United States shall be entitled to recover on the basis of joint and several liability from any transferor, transferee, or successive transferee of the facility an amount determined in accordance with this subpart.

(b) If any facility at any time within 20 years after the completion of the grant-assisted construction or modernization ceases to be a public or other non-profit facility that would have been eligible for a grant under the statute pursuant to which the grant was awarded, the United States shall be entitled to recover from the owners of the facility an amount determined in accordance with this subpart.

§ 124.704 Notification of sale, transfer, or change of use.

(a) The transferor of a facility that is sold or transferred as described in § 124.703(a), or the owner of a facility which ceases to be a public or other nonprofit facility as described in § 124.703(b), shall provide the Secretary written notice of such sale, transfer, or other change not later than 10 days after the date on which the sale, transfer, or change occurs.

(1) *"Transfer."* For purposes of this subpart, a transfer occurs when a facility is conveyed to another entity through lease, merger, bankruptcy, foreclosure, or other arrangement.

(2) *"Cease to be."* For purposes of this subpart,

(i) A facility "ceases to be" a facility for which a grant could have been made under the statute pursuant to which the grant was awarded when it is no longer operated as such a facility; and

(ii) A facility "ceases to be a public or nonprofit facility" when an entity that is not a public or other non-profit corporation or association assumes management responsibilities with respect to the facility which, in the Secretary's judgment, are so pervasive as to constitute operation of the facility. The manager will not be deemed to be the operator of the facility if the management agreement contains both of the following provisions:

The Board of Directors of the facility retains authority to terminate the agreement at any time upon reasonable notice to the contractor.

No employee of the contractor may be a member of the facility's Board of Directors.

In the absence of either of these provisions the Secretary will consider the degree of control granted to the managing organization over patient admission, determination of what services will be provided, and charges for services provided in the facility.

(b) *Content of Notice.* The notice required by paragraph (a) of this section shall be sent to the Secretary by certified mail, and shall contain or be accompanied by

(1) The date of the sale, transfer, or other event that gives rise to the notice;

(2) Copies of any sales contracts, lease agreements, management contracts or other documents pertinent to the event giving rise to the notice;

(3) Estimates of current assets, current liabilities, book value of equipment, the expected value of land on the new owner's books, and the remaining depreciation for all fixed assets involved in the transaction calculated on a straight line basis using commonly adopted expected useful lifetimes.

(c) *Failure to provide notice.* Failure to provide the information required by paragraph (b) will be considered failure to provide the notice required by this section. In any case in which such information has not been provided, the Secretary will, promptly upon receiving an incomplete notice or otherwise discovering that a sale, transfer or other event giving rise to a recovery may have occurred, send a letter to the owner of the facility requesting the information needed to calculate a recovery amount.

(Approved by the Office of Management and Budget under control number 0915-0099)

§ 124.705 Amount of recovery.

(a) Except as provided in § 124.706, the amount that the United States shall be entitled to recover under this subpart is that amount bearing the same ratio to the then value of so much of the facility as constituted an approved project (or projects) as the amount of Federal participation bore to the cost of the construction or modernization under such project (or projects).

(b) The then value of the facility will be based on:

(1) The transaction value in the case of an arms-length sale or transfer, or

(2) A depreciated reproduction value in the absence of an arms-length sale or transfer or if the buyer fails to provide, within 60 days after the date of the Secretary's letter described in § 124.704(c), the information which, in the judgment of the Secretary, is necessary to establish, adjust, and apportion a transaction value. As used in this section, "transaction value" means in the case of a sale, the sale price, and in the case of a lease, the value of the lease plus the residual value of the facility at the termination of the lease (i.e., the reproduction value or, if appropriate, an alternative use value).

(c) The transaction value will be adjusted to account for the purchase or lease of other assets and the assumption of liabilities associated with the transaction. To determine the amount of Federal recovery, the adjusted value will be apportioned to the grant-aided assets by the ration of the remaining useful lifetime values of those assets to the sum of the remaining useful lifetime values of all assets not previously accounted for in adjusting the transaction value.

(d) A depreciated reproduction value will be established by calculating a reproduction value using construction cost indexes or current costs per square foot for construction, depending on which is more relevant to the type of construction associated with the grant. This reproduction value will then be adjusted by the ratio of the remaining useful life to the total useful life for the assets involved.

(e) In calculating the recovery amount, the Secretary will include as Federal participation any grant assistance received by the facility under an authority listed in § 124.701 and any assistance supplementary to that assistance received for the construction or modernization of the facility under the Public Works and Economic Development Act of 1965 (42 U.S.C. 3121, et seq.) or the Local Public Works Capital Development Act of 1976 (Pub. L. 94-369).

§ 124.706 Calculation of interest.

(a) In addition to the amount of recovery calculated under § 124.705, the United States shall be entitled to recover interest on such amount in accordance with this section at the rate determined by the Secretary based on the average of the bond equivalent of the weekly ninety-day U.S. Treasury bill auction rate for the quarter previous to the quarter in which interest begins to accrue under this section.

(1) *Change of status before July 18, 1984.* For facilities that were sold or transferred or which ceased to be public or other nonprofit facilities before July 18, 1984, interest will be charged beginning August 17, 1984, or 180 days after the date of such sale, transfer or other, whichever is later, and ending on the date the amount the United States is entitled to recover is collected.

(2) *Change of status after July 17, 1984.* For facilities that are sold or transferred or which cease to be public or other nonprofit facilities after July 17, 1984, interest will be charged beginning 180 days after receipt by the Department of the notice required under § 124.704; *Provided, That* if such notice is not provided as prescribed, interest will be charged beginning on the date of the sale, transfer, or change of use, and ending on the date the amount which the United States is entitled to recover is collected.

(b) The Secretary may waive interest charges that result from delays caused solely by the Department.

§ 124.707 Waiver of recovery where facility is sold or transferred to a proprietary entity.

(a) *Conditions of the waiver.* The Secretary may waive the recovery rights of the United States arising under § 124.703(a) if the entity to which the facility was sold or transferred:

(1) Has filed a written request for the waiver within the time limits prescribed by this section;

(2) Has established an irrevocable trust in accordance with this section, in an amount equal to the greater of the amount that would otherwise have been recovered pursuant to § 124.705 (including accrued interest as calculated under § 124.706) or twice the cost of the remaining uncompensated services obligation of the facility as of the date of the change of status, that will be used by the entity only to provide services to those unable to pay in accordance with the requirements of Subpart F of this Part; and

(3) Has agreed to comply with the community service regulations set out in Subpart G of this Part.

(b) *Procedures for obtaining waiver.* (1) Within 30 days after the date of receipt of the information described in § 124.704(b), the Secretary will send a letter to the new owner of the facility advising of the United States' right of recovery and the opportunity to obtain a waiver. For the purpose of advising the new owner of the amount to be placed in the irrevocable trust should the owner wish to obtain a waiver, the letter will also state the dollar amount of the remaining uncompensated care obligation and the amount that would be due under § 124.705, computed as follows:

(i) *Computation of uncompensated care obligation.* (A) For a facility which changes status before the date that Subpart F of this part is effective for the facility, the remaining uncompensated services obligation is zero.

(B) For a facility which changes status after the date that Subpart F of this part is effective for the facility, the Secretary will multiply the annual compliance level, computed under the 10% method specified in 42 CFR 124.503(a)(1)(ii), for the fiscal year in which the change of status occurs times the number of years remaining in the facility's uncompensated services obligation. From this amount, the Secretary will subtract amounts of excess or add amounts of deficit for each fiscal year prior to the change of status for which the Secretary has previously conducted an audit of uncompensated services accounts. Excess and deficits will be adjusted by the percent change in the National Consumer Price Index for Medical Care between the year in which the excess or deficit occurred and the year in which the status change occurred. For each fiscal year prior to the change of status which the Secretary has not audited, the Secretary will add to the remaining obligation an amount equal to the annual compliance level in each such year adjusted by the percent change in the National Consumer Price Index for Medical Care between that year and the year of the status change. The amount computed as the total remaining obligation will then be multiplied by two. If the transferee chooses to accept the Secretary's calculation, no further assessments will be made of uncompensated care provided prior to the change of status date. If the transferee does not accept the calculation, the transferor or transferee may hire, and may charge against the irrevocable trust established under this section, an independent auditor to certify the compliance level and any excess or deficit for the period from May 18, 1979, up to and including the date of the change of status, using standard Departmental procedures supplemented with instructions provided by the Secretary, and submit the results in accordance with paragraph (b)(2)(ii) of this section. The audit may be conducted for any years *not* included in a previous site assessment conducted by the Department. If the Secretary agrees that a change is appropriate, the Secretary will use this information to adjust the calculation as set out in paragraph (b)(3) of this section. If the independent auditor certifies that qualified care was rendered either at the facility or at a replacement facility operated by the transferee between the date of the change of status and the date of establishment of the trust, and the

Secretary agrees, the post transfer level of care shall not affect the calculation of the total remaining uncompensated care obligation to be doubled, but instead shall be recognized as a credit to be drawn from the trust as provided in paragraph (c)(1)(ii) of this section. In the case of a facility with respect to which a grant was made under Title XVI of the Act, the remaining period of obligation will be the remainder of the expected useful life of the facility, as follows: 40 years for buildings, 30 years for additions, 20 years for building renovations, 20 years for fixed equipment and 12 years for major movable equipment.

(ii) *Computation of recovery amount.* The Secretary will determine the recovery amount as provided in § 124.705.

(2) Within 60 days following the date of the Secretary's letter provided pursuant to subparagraph (1), the owner of the facility shall notify the Secretary in writing that it either:

(i) Accepts the trust fund amount for the waiver as offered by the Secretary;

(ii) Provides a detailed statement of an alternative determination of the recovery amount or an independent audit of the remaining uncompensated services obligation as described in paragraph (b)(1)(i) of this section; or

(iii) Does not seek a waiver under § 124.707. Failure to provide a timely response to the Secretary under this subparagraph will be considered an election not to seek the waiver.

(3) Within 30 days following the receipt of the owner's views concerning the calculation, and after considering those views, the Secretary will send a final letter providing the Secretary's determination of twice the remaining uncompensated care obligation and the recovery amount under § 124.705. The amount to be placed in the irrevocable trust will be the higher of those two figures. (See paragraph (a)(2) of this section.)

(4) Within 30 days of the date of the final letter, the owner of the facility shall notify the Secretary in writing whether or not it accepts the terms of the waiver. Failure to provide timely notice to the Secretary under this subparagraph will be considered an election not to accept the waiver.

(c) *Establishment of the trust.* (1) Within 60 days of the date of its acceptance of a waiver under paragraph (b)(2) or (b)(4) of this section, the owner shall begin delivering services to those unable to pay in accordance with Subpart F of this part under an irrevocable trust established in the amount calculated pursuant to paragraph (b). *Provided, that*

(i) The owner shall provide a copy of the trust documents to the Secretary and no trust shall be considered established until the trust documents have been approved by the Secretary; and

(ii) The owner may credit against the trust any uncompensated services provided in accordance with subpart F of this Part between the date of the change of status of the facility and the establishment of the trust. For an owner to receive the credit before the establishment of the trust and deposit of funds therein, the auditor's report covering the post-transfer period shall be submitted with the notification of acceptance of the waiver, and in any event, not later than 30 days from the date of the Secretary's final letter described in paragraph (b)(3) of this section. Within 30 days following the receipt of the auditor's report, the Secretary will notify the owner of the allowable credit, if any. If the auditor's report is not timely submitted, the trust must be established and fully funded, in accordance with the time limits imposed by paragraph (c)(1) of this section, and the Secretary will notify the owner of the allowable credit, if any, within 30 days of the date of the establishment of the trust or within 30 days of the receipt of the report, whichever is later.

(2) The trust shall be administered by a Trustee who is neither an employee of the transferee nor an employee of a subsidiary or of the parent institution of the transferee.

(3) The trust shall provide that the trust corpus and income may be invested only in U.S. Government or U.S. Government insured securities.

(d) *Use of the trust.* The corpus and income of the irrevocable trust shall be used to pay for the costs of uncompensated services, which may include

reasonable costs of establishing and administering the trust and the cost of the independent audit described in paragraph (b)(1)(i) of this section, until the trust is exhausted.

(Approved by the Office of Management and Budget under control number 0915-0099)

§ 124.708 Waiver of recovery—good cause for other use of facility.

The Secretary may for good cause waive the recovery rights of the United States arising under § 124.703(b). In determining whether there is good cause under this section for releasing the applicant or other owner of the facility from its obligation, the Secretary will take into consideration the extent to which:

(a) The facility will be devoted by the applicant or other owner to use for another public or nonprofit purpose whch will promote the purpose of the Act;

(b) There are reasonable assurances that for the remainder of the 20-year period other public or nonprofit facilities not previously utilized for the purpose for which the facility was constructed will be so utilized and are substantially equivalent in nature and purpose.

§ 124.709 Withdrawal of waiver.

(a) Any waiver granted under this subpart is conditioned upon the recipient of the waiver carrying out the obligations imposed by § 124.707 or § 124.708 as applicable.

(b) The Secretary will monitor compliance with the community service and uncompensated care obligations of any entity that receives a waiver.

(c) Should a recipient of a waiver fail to comply with the applicable conditions, the Secretary will withdraw the waiver and seek recovery based on the value of the facility on the date the right of recovery first arose under § 124.703.

(d) No waiver will be withdrawn until the recipient has been notified in writing by the Secretary of the noncompliance and has failed to take corrective action within 90 days after the date of such notice.

(e) Should the waiver be withdrawn, the amount of the Government's recovery will be the amount set out in the Secretary's determination letter as described in § 124.707 (b)(1) or (b)(3) as applicable plus interest from the date of the notification sent in accordance with paragraph (d) of this section.

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Redesignation Table 1

The following table shows the effect of recodification on the regulations contained in Part 72 which were redesignated in Title 21 and appeared at 40 FR 5620, Feb. 6, 1975.

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72.1 (extracted)	1240.3, 1250.3
72.2	1240.54
72.3	1240.30
72.4	1240.10
72.11	1240.40
72.12	1240.50
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72.15	1240.45
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72.23	1240.75
72.24	1240.60
72.26	1240.62
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72.103	1240.90
72.104	1240.95
72.105	1240.86
72.111	1250.80
72.112	1250.81
72.113	1250.82
72.114	1250.83
72.115	1250.84
72.116	1250.86
72.117	1250.85
72.118	1250.87
72.119	1250.89
72.120	1250.90
72.121	1250.93
72.122	1250.95
72.123	1250.96
72.131	1250.60
72.132	1250.61
72.133	1250.62
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72.135	1250.65
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72.137	1250.67(b)
72.139	1250.67(c)
72.140	1250.70
72.141	1250.75
72.142	1250.79
72.146	1250.40
72.147	1250.41
72.148	1250.42
72.149	1250.44
72.150	1250.50
72.151	1250.45
72.152	1250.49
72.153	1250.43
72.154	1250.51
72.155	1250.53
72.156	1250.52
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72.162	1250.21
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72.167	1250.28
72.168	1250.30
72.169	1250.33
72.170	1250.34
72.171	1250.39
72.172	1250.38
72.173	1250.32
72.174	1250.35
72.181	1240.20

Redesignation Table 2

At 42 FR 52826, September 30, 1977, regulations formerly appearing in Title 42 as Part 101 were redesignated and transferred into Parts 460 through 480 of this title.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section (Chapter I)	New section (Chapter IV)
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101.17	460.17
101.18	460.18
101.19	460.19
101.20	460.20
101.21	460.21
101.22	460.22
101.23	460.23
101.24	460.24
101.25	460.25
101.26	460.26
101.27	460.27
101.28	460.28
101.29	460.29
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101.56	460.56
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101.102	461.2
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101.104	461.4
101.105	461.5
101.106	461.6
101.107	461.7
Subpart N	*Part 473*
101.1401	473.1
101.1402	473.2
101.1403	473.3
101.1404	473.4
101.1405	473.5
101.1406	473.6
Subpart U	*Part 480*
101.2101	480.1
101.2102	480.2
101.2103	480.3
101.2104	480.4
101.2105	480.5
101.2106	480.6

Redesignation Table 3

At 52 FR 36747, September 30, 1987, regulations formerly appearing in Title 42 as Part 110 were redesignated and transferred into Part 417 of this title.

For the convenience of the user, the following table shows the relationship of the redesignated sections.

Old section (Chapter I)	New section (Chapter IV)
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110.101	417.100
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110.207	417.116
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List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations which were made by documents published in the FEDERAL REGISTER since January 1, 1973, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters and parts as well as sections for revisions.

For the period before January 1, 1973, see the "List of CFR Sections Affected, 1949-1963 and 1964-1972," published in three separate volumes.

1973

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65 Added 28290
71.1 (w) revised 16861
71.31 Revised 16861
(a)(1) corrected 19222
71.46 Revised 16861
71.49 (a) revised 16862
74.1 (i) revised 10721
74.10 (d) revised 10721
74.20 (a), (c), and (d) revised 10721, 10722
74.21 (a) and (b) revised 10722
74.42 (d) revised 10722
74.47 Heading revised 10722
78 Redesignated as 21 CFR Part 278 1926
80 Added 16645
84 Added 11459
84.2 (e) corrected 14940
87.14 (b) amended; (c) revised 26199
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